

ATTACHMENT

Date	Event
[REDACTED]	Eagle submits ANDA with FDA.
April 8, 2020	During the April 8, 2020 teleconference with the Court to discuss the Covid-19 related postponement of the scheduled trial, Eagle [REDACTED] Ex. A (4/8/20 Tr. at 7:21-23, 8:17-19, 9:22-25). On that basis, the Court sets another status conference for May 18. <i>Id.</i> at 11:13-16; 22:14-17.
May 18, 2020	Eagle represents to the Court that the [REDACTED] Ex. B (5/18/20 Tr. at 33:13-34:3, 37:2). The Court orders Eagle to inform it as soon as it hears back from the FDA. <i>Id.</i> at 40:3-4.
June 19, 2020	FDA [REDACTED] . Ex. C at 5.
June 24, 2020	Eagle [REDACTED] Ex. D.
July 30, 2020	Eagle [REDACTED] Ex. E (7/30/20 Eagle letter to FDA) attachment at pp. 19-20 of the PDF.
August 28, 2020	The FDA [REDACTED] Ex. F (8/28/20 FDA letter) at 2 (<i>italics added</i>).
[REDACTED]	[REDACTED]

Date	Event
September 24, 2020	Eagle [REDACTED] Ex. G (9/24/20 [REDACTED] at 4-8.
September 26, 2020	The FDA [REDACTED] Ex. H (9/26/20 FDA Acknowledgement).
October 4, 2020	FDA emails Eagle to state that it has a priority review status, [REDACTED] Ex. I (10/4/20 FDA email).
October 17, 2020	30 Month stay expires.
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]

EXHIBIT A

1 IN THE UNITED STATES DISTRICT COURT
2 IN AND FOR THE DISTRICT OF DELAWARE

3 - - -

4 PAR PHARMACEUTICAL, INC., : CIVIL ACTION
5 PAR STERILE PRODUCTS, LLC, :
6 and ENDO PAR INNOVATION :
7 COMPANY, LLC, :
8 :
9 Plaintiffs, :
10 :
11 :
12 vs. :
13 :
14 :
15 EAGLE PHARMACEUTICAL INC., :
16 :
17 :
18 Defendant. : NO. 18-823-CFC

19 - - -

20 Wilmington, Delaware
21 Wednesday, April 8, 2020
22 2:33 o'clock, p.m.
23 ***Telephone conference

24 - - -

25 BEFORE: HONORABLE COLM F. CONNOLLY, U.S.D.C.J.

 - - -

 APPEARANCES:

 FARNAN LLP
 BY: MICHAEL J. FARNAN, ESQ.

 -and-

 Valerie J. Gunning
 Official Court Reporter

1 APPEARANCES (Continued):

2
3 DECHERT LLP
4 BY: ROBERT D. RHOAD, ESQ.
(Princeton, New Jersey)

5 -and-

6 DECHERT LLP
7 DANIEL ROBERTS, ESQ.
(Princeton, New Jersey)

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9 DECHERT LLP
10 BY: MARTIN J. BLACK, ESQ.
(Philadelphia, Pennsylvania)

11 Counsel for Plaintiffs

12
13 POTTER, ANDERSON & CORROON LLP
14 BY: BINDU A. PALAPURA, ESQ.

15 -and-

16 KIRKLAND & ELLIS LLP
17 BY: JEANNA M. WACKER, ESQ. and
18 BRYAN HALES, ESQ.
(New York, New York)

19 Counsel for Defendant

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1 just dealing with scheduling, to just keep it among the
2 parties. I'm not one that generally likes to close off
3 proceedings, but in the normal course, this type of
4 telephone call would not have been a public event, and so
5 that's why I did it in this circumstance.

6 So we've got a trial scheduled for May 18th and
7 I'm just concerned given the current circumstances of the
8 world that that is not really a doable date.

9 Do the plaintiffs have any position on this?

10 MR. BLACK: Yes, Your Honor. It's Martin Black.

11 My understanding from talking to Mr. Farnan is
12 that there's really no way we could make it work. In
13 addition to the likelihood of some extension to the current
14 situation, there's a law in Delaware that says that anybody
15 who enters Delaware from out of state has to quarantine for
16 two weeks before they can do anything, which would make it
17 impossible for us to go to Delaware and prepare even though
18 I only live a few miles up here in Philadelphia.

19 We have an expert from California who is working
20 at a hospital right now. I don't know how we could get
21 everybody to Delaware and get them to the courthouse without
22 violating Delaware law and I don't even know whether we
23 would be out of quarantine by the 18th. It seems unlikely.
24 So I think we probably are going to need to make some
25 adjustment.

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1 P R O C E E D I N G S

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5 (The following telephone conference commenced at
6 2:33 p.m.)

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8 THE COURT: Good afternoon, everyone. So let's
9 begin with the plaintiffs, please.

10 MR. FARNAN: Good afternoon, Your Honor. It's
11 Michael Farnan for the plaintiff, and with me on the line is
12 Martin Black, Bob Rhoad and Dan Roberts from Dechert.

13 THE COURT: All right. And then for the
14 defense?

15 MS. PALAPURA: Good afternoon, Your Honor.
16 Bindu Palapura from Potter Anderson, and with me on the line
17 today is Bryan Hales and Jeanna Wacker from Kirkland &
18 Ellis.

19 THE COURT: All right.

20 MR. HALES: Good afternoon, Your Honor.

21 THE COURT: Good afternoon. And just for the
22 parties, I will let you know, we were contacted, our
23 chambers was this morning by e-mail by -- well it's not
24 clear who, but asking to participate in this call, and I
25 just decided, because I thought it would be very brief and

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1 So Your Honor knows, the 30-month stay in this
2 case expires on October 17th, and somewhat oddly, the
3 defendant does not have tentative approval yet. As I think
4 the Court is probably aware, the FDA grants tentative
5 approval when the application is ready except for the
6 30-month stay, but they still don't have approval yet, so it
7 may be that this is all a little premature.

8 The final issue is, we have another trial on
9 these same patents with I think five co-defendants scheduled
10 for January, so one somewhat elegant solution would be to
11 move this trial to next January with the others. We would
12 have to deal with the 30-month stay. If they obtained
13 approval, we could hopefully do it by agreement, but if not,
14 we could do a PI on the papers regardless of the Court's
15 status.

16 So those are our thoughts. You know, we're
17 trying to be creative. But I don't even see a trial date on
18 May 18th.

19 THE COURT: Okay. And what do the defendants
20 have to say?

21 MR. HALES: Thanks, Your Honor. This is Bryan
22 Hales on behalf of Eagle.

23 So Mr. Black's suggestion to move to January is
24 one that was raised before in the last call we had. We
25 still don't agree to that, so just -- and I know the Court

1 understands this from our last call, where we were having --
2 THE COURT: Look, I have no recollection of your
3 last call.

4 MR. HALES: Fair enough.

5 THE COURT: It's impossible. If you want to
6 just tell me, I'm happy to --

7 MR. HALES: Fair enough. Your Honor after our
8 last call had kindly put in a very fast briefing schedule
9 because of the significance of that October expiration of
10 the 30-month stay, and just so you know, from Eagle's
11 perspective, we have two really important competitive
12 interests.

13 One is that we're a first filer with statutory
14 exclusivity over some of the other proposed ANDA filers, and
15 the other is that for a few where we don't have the
16 statutory exclusivity, frankly, the company just invested
17 time and effort into being the first one to get its ANDA in,
18 and so while we, to be clear, understand the challenges in
19 May, and I will get to that in just a moment, the fact that
20 we have the statutory exclusivity, and for those where we
21 don't have that, we had a May trial as compared to their
22 January trial. Those differences in time are immensely
23 important to the company in terms of its ability to protect
24 its investment that it put into this particular ANDA
25 product.

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1 And so with that said, you know, moving back to
2 January would eat up the statutory exclusivity and the other
3 logistical or the investment-based advantage that we have
4 over those entities.

5 And so our goal recognizing in these very odd
6 circumstances that it doesn't seem likely that we could have
7 a trial in May given the things that Mr. Black has outlined,
8 our request would be that we try to figure out when -- you
9 know, pick another date that is as soon as we reasonably can
10 that is available for the Court where we think with some
11 blessings that we're in the clear to actually proceed at
12 that time, whether that's later in June or July.

13 I mean, obviously, nobody has a crystal ball.
14 We don't know when we are going to come out of this, but
15 what we want the Court to understand is that it is really,
16 really important to the client that we try to do whatever we
17 can to try to protect the exclusivity and the time that the
18 company invested an awful lot into.

19 Oh, and finally -- finally, Your Honor, sorry.
20 On the tentative approval question, there's no guarantee, of
21 course, but our expectation, and we've been in touch with
22 our client on this, is [REDACTED]
23 [REDACTED], so that will play out
24 how it plays out, but there's nothing about that situation
25 that would cause us to agree or agree that a January trial

1 with the others is a good idea.

2 THE COURT: All right.

3 MR. BLACK: Obviously, we'll do whatever makes
4 sense with your calendar, Your Honor. It is odd they don't
5 have approval from the FDA yet, so the urgency is not
6 normally what it is at this stage. We think they filed
7 the application early and incomplete and now they have
8 problems.

9 We actually -- their stability data that they
10 have been running tests on which they have not produced to
11 us, which they should have, we don't know what's going on
12 and nobody can know when the FDA is going to give an
13 approval or if they will do so.

14 THE COURT: Well, can I just ask. So to the
15 defendants, do you expect us to go to trial when you didn't
16 have approval?

17 MR. HALES: Well, Your Honor, our belief is that
18 we were going to have approval in [REDACTED]. That's the
19 latest understanding that I had the from the client.

20 THE COURT: Do you recall -- what did you tell
21 me, if you recall, on the last phone call about the expected
22 approval date?

23 MR. HALES: To be honest, Your Honor, I don't
24 recall it coming up on the last call.

25 MR. BLACK: I know they've been telling us

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1 forever that they are just about to get approval. Nobody
2 knows. In the normal course you don't know whether you
3 are going to get approval. Now with what's going on, who
4 knows what that group in the FDA is doing and how active
5 they are.

6 My only point is, Your Honor, if we're going to
7 set a trial and lock something in in July or August or
8 something like that when they don't have approval and then
9 we're going to retry the same patent, the same validity
10 defenses in January with a bunch of other defendants, you
11 know, it's going -- we're going to have to expend an
12 enormous sum trying the case twice, but that's us.

13 We have commercial issues. They have commercial
14 issues. Your Honor has a scheduling docketing pandemic
15 issue. We will do whatever makes sense from your
16 perspective. One thing we could do is wait until they get
17 tentative approval. If they get it in [REDACTED], we can
18 regroup and figure out whether we can do a trial at some,
19 you know, some form. We'll, of course, do whatever works
20 for the Court.

21 MR. HALES: Your Honor, it's Bryan Hales again.

22 Just the -- [REDACTED] is the date by which the
23 FDA is supposed to respond to our last submission, which is
24 why we have understood, you know, and our client believes
25 that they are going to have approval. I absolutely -- that

1 is in the FDA's hands, but that's what we were going on, and
2 just by point of reference, I mean, it does happen that
3 trials happen without, where you're still waiting to get
4 tentative approval and sometimes that comes even between the
5 trial and the decision. I think that's kind of the
6 structure that -- I wasn't involved in the case at the very
7 first scheduling, Your Honor, so I can't comment on that,
8 but --

9 MR. BLACK: I think he made an important
10 clarification, which is if they're expecting a response on a
11 particular day from the FDA, but the last submission that
12 they made was massive, and they don't know what's going to
13 be in that response.

14 So when Mr. Hales says he thinks they are going
15 to get approval, their client is hoping to get approval in [REDACTED]
16 [REDACTED] but all they know is that the FDA is likely to
17 respond on a particular day and that response could very
18 well be you've got more work to do.

19 I don't think it was accurate to represent that
20 they know they're going to get approval. We could revisit
21 if they get approval, but they don't have it yet.

22 THE COURT: All right. Well, we're going to
23 cancel the trial for May 18th. I just don't see how that's
24 possible, and I think the better course would be to plan on
25 a phone call in May and just to revisit this.

1 reasons that -- you kindly heard us, heard them out, it
2 wasn't me, but heard it out for a couple of minutes, and one
3 of the reasons that that wasn't accepted by the Court as a
4 way to proceed was that the summary judgment motion we were
5 proposing wouldn't resolve the entire case because it didn't
6 cover all six patents that were then at issue.

7 So at that time Par dropped three of the patents
8 and the same issue of summary judgment would be case
9 dispositive and it's a noninfringement only issue, and in
10 sixty seconds I can tell you why I think it is so
11 compelling.

12 In light of the situation, our hope was that the
13 Court would consider letting us do that. And the quick
14 story is that all of the three remaining asserted patents
15 have a requirement of a pH level between 3.7 and 3.9 or
16 specifically 3.8, within that range.

17 Eagle's proposed ANDA requests approval of a
18 drug product with a specified [REDACTED], outside of
19 the range of all of the claims and Par is only asserting
20 literal infringement. They would have no DOE case.

21 So if we get approval for that, Eagle is not
22 able to sell anything but a product that has [REDACTED]

[REDACTED], and that [REDACTED]

[REDACTED]

25 And the case law is clear that when you have an

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1 It's going to be very, very difficult. It's
2 very difficult to move stuff, so I'm mindful of the benefits
3 of being the first out there on the market and that's why it
4 looks like we scheduled the trial for when we did, but there
5 are a lot of equities competing here.

6 So I think what we'll do, we'll take it -- I
7 don't think it would be beneficial -- I don't even know if
8 it's possible to schedule a trial between May and September,
9 for instance, so let's just see.

10 So [REDACTED]

11 [REDACTED] Is that what you said?

12 MR. HALES: Correct, Your Honor, yes.

13 THE COURT: So why don't we have a call -- why
14 don't we just do the call on May 18th, the original first
15 day of trial, and we can hopefully know more then and then
16 revisit this. All right?

17 MR. HALES: Your Honor, this is Bryan Hales.

18 Could I have a moment to raise one other
19 proposal in relation to this?

20 THE COURT: Sure. Yes.

21 MR. HALES: So back in the early -- the first
22 scheduling conference, one of the things that was raised by
23 defendants was the possibility of filing a motion for
24 summary judgment, which I understand the Court normally
25 doesn't have in bench trial situations. And one of the

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1 ANDA specification that resolves the question of
2 infringement like here, where the claim has something
3 required and the ANDA specification requires something
4 different, the ANDA spec controls I think largely because
5 that's all we would have approval to sell. And so that is
6 one, I think that's -- we believe it's a clean legal issue
7 that would resolve the case and resolve everything that's
8 left in the case at this point.

9 The only thing that Par has -- the second point
10 to that, the only thing that Par has that they are using to
11 keep this case going forward, and these are two independent
12 grounds to win. If we're right on the law, which I believe
13 we are, the spec controls, it's the end of the case. Par is
14 going to have to argue that it doesn't. And then what they
15 are left with, if the spec doesn't control, the ANDA
16 specification, [REDACTED] And
17 contrary to what Mr. Black has said, we produced all of our
18 stability data, [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED], and there's a body of clear
22 Federal Circuit law on this as well that when you have
23 literally one or a small number of anomalous outlier points,
24 that's not enough to carry the burden on infringement.

25 So those two issues we think are legal issues

1 that could dispose of the case, and particularly with the
2 circumstances and the uncertainty about when there could be
3 a trial, we request permission to present that motion to
4 Your Honor, again noninfringement only, and those two
5 issues.

6 THE COURT: What do the plaintiffs have to say?

7 MR. BLACK: Your Honor, Martin Black for the
8 plaintiff.

9 So they made [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED] Some of those tests have been submitted
15 to the FDA. Some of them, we're not sure what has been
16 submitted. We know that they have additional stability data
17 on batches that are right now being tested and they have
18 refused to give us the data for that.

19 We do not agree with them on the facts
20 therefore. [REDACTED]

21 [REDACTED], and we
22 don't --

23 THE COURT: Wait. Let me just ask. So,
24 Mr. Hales, let's just address that point first. Does your
25 client have a batch that falls outside the range that it can

1 nine, twelve months, a pH read is taken.

2 [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

6 THE COURT: So is that --

7 MR. HALES: Every other test --

8 THE COURT: Sorry to interrupt.

9 MR. HALES: Yes. Thank you.

10 THE COURT: If it has a 24-month shelf life and
11 you did the measurement on the last day of the twenty-fourth
12 month, how do you sell that product at all? Isn't that
13 product gone?

14 MR. HALES: You can't, correct.

15 THE COURT: So then why didn't you just at
16 the outset say you would -- okay. So then as a factual
17 matter -- fair enough. I guess it's a little ambiguous.
18 So this one particular batch, it's done. It's
19 over.

20 MR. HALES: That's correct.

21 THE COURT: All right. So, Mr. Black, so why is
22 that an issue?

23 MR. BLACK: Yes, Your Honor. This is an ANDA
24 case. The product is not on the market, obviously, and what
25 they did is they made three sample batches that they

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1 sell?

2 MR. HALES: There's no batch, Your Honor. I
3 believe what Mr. Black is referring to is what I said. [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]. That's the anomaly law
10 that we talked about. [REDACTED]
[REDACTED]

12 THE COURT: All right. So how does this work?
13 You said there were multiple measurements done on this one
14 batch. Is that correct?

15 MR. HALES: Yes, that's correct. That's
16 correct.

17 THE COURT: All right. How big is that batch?

18 MR. HALES: I don't know the answer to that,
19 Your Honor. It's something we could obviously find out, but
20 off the top of my head, I don't know the answer. What I do
21 know is that because these products have an initial pH and
22 then they have a shelf life during which these drugs can be
23 administered, their pH is measured at the release point and
24 then certain amounts of them go into stability testing or
25 monitoring and then periodically, you know, one, three, six,

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1 submitted the data from with their ANDA, hundreds of points.
2 They look at the -- they look at the status at 1
3 month, 3 months, 6, 9, 12 up to 24. They need to get
4 24-month approval, because that's what our product has. If
5 they get a product that's only good for 12 months or 15,
6 it's not going to be saleable.

7 So they have asked for 24 months. They
8 submitted data to the FDA which indicate that our experts
9 say before the 24 months, I don't know how many months, that
10 specific batch was in the pH range. We now have to say
11 what's going to happen when they make the product and it
12 goes out into the public, and that's evidence of
13 infringement. We'll be selling some product which falls
14 within our spec.

15 Similarly, under 271(a) --

16 THE COURT: But what I don't get is, when you
17 say it falls within the spec, if the FDA says they can't put
18 it on the market except as it falls within the range that,
19 as I understand it, does not fall within the range covered
20 by the patent, then how do you have infringement?

21 MR. BLACK: If the actual product they sell ends
22 up falling within the range over the period of its life,
23 then that's infringement. That's infringement.

24 They can sell the product at a particular level,
25 but [REDACTED] when they sell it to 3.7 at any

1 time over the 24 months, then there's infringement, and we
2 have expert evidence on this. The experts are going to
3 disagree about what is going to happen in the real world and
4 it's not the sort of thing which is ripe for summary
5 judgment.

6 MR. HALES: So, Your Honor, Bryan Hales again.
7 If I can just throw two quick thoughts in there
8 and I can name a case.

9 One thing that Mr. Black says that's true, we
10 don't have a product on the market yet and that's one of the
11 reasons that the Bayer case, which is a Federal Circuit
12 case, says that the ANDA specification controls. Right?

13 One thing I clearly disagree with Mr. Black on
14 is, if we get approval to market a product at [REDACTED] we
15 can't sell anything but that. That's what the Bayer case
16 makes clear why that specification that we're seeking
17 approval controls the question of infringement.

18 The second point, because the product isn't sold
19 yet, clearly, we can't sell the batch that has the 3.8.
20 It's way past its life, so Mr. Black is wrong about that.
21 But these anomaly cases, this anomaly line of cases exists
22 in this context because what Par has to try to say is that
23 there's some theoretical expectation that our pH is going
24 to, against the specification and against the process
25 controls [REDACTED] into the claimed

1 I've got to wrap this up because I've got to move on. But,
2 you know, are you willing to stipulate to what his expert
3 says?

4 MR. HALES: Not that it's expected it's going to
5 [REDACTED] because of the anomaly line of cases.

6 Clearly, we would accept, we accept that there is [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

12 What the Federal Circuit cases say, like there's
13 a case called Ferring versus Watson Labs, say that in the
14 ANDA context, when you are looking at whether the patent
15 owner can carry the burden of establishing that it's more
16 likely than not that something like that will happen again,
17 it is not enough to have an anomalous data point. And there
18 are cases where there are for or five data points out of a
19 hundred and they say you can't carry your burden on
20 infringement as a matter of law when you've got a small
21 number of data points.

22 And what we're saying is out of all of the tests
23 that we've done on all of the batches that we've done over
24 all of the time periods, [REDACTED]
[REDACTED] and they can't carry the burden on that as a

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1 range, the approved amount of [REDACTED] into the
2 claimed range of 3.7 to 3.9. And the only thing that
3 anybody has to go on is the set of data.

4 THE COURT: Right.

5 MR. HALES: And so one point is an anomaly.
6 Sorry, Your Honor.

7 THE COURT: All right. Hold on.

8 So, Mr. Black, do you agree with that, that that
9 is kind of the nub of the dispute?

10 MR. BLACK: I think that's the nub of the
11 dispute and the experts disagree with whether if they sell
12 something at [REDACTED]
[REDACTED]
[REDACTED]

15 All they have to do is move [REDACTED] and we
16 have an actual example.

17 THE COURT: All right. Just let me stop you.
18 Sorry. Mr. Hales --

19 MR. HALES: Yes.

20 THE COURT: -- if you stipulate for purposes of
21 summary judgment that the product could over time -- I mean,
22 see, if it's a dispute among experts, then we don't have
23 summary judgment. But if you are telling me --

24 MR. HALES: Sorry, Your Honor.

25 THE COURT: No, no. I'm just trying to, and

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1 matter of law.

2 MR. BLACK: [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

6 Our expert said that there's infringement and
7 that if they make this product the way they are planning to
8 make it, there's a lot of detail about how they're making
9 it, it is more likely than not that product will be on the
10 market [REDACTED]
[REDACTED]
[REDACTED]

14 [REDACTED] and they will have snuck through.

15 They will not accept our expert's testimony for
16 the purposes of the summary judgment motion. You just heard
17 them say that. So I don't see how they can get summary
18 judgment. If they are going to dispute our expert's,
19 qualified expert's opinion as to the facts, we're going to
20 have to have a trial.

21 MR. HALES: Well, with respect, Your Honor, I
22 think Mr. Black is wrong on some of the data. [REDACTED]
[REDACTED]y, and
23 a variety of --

24 MR. BLACK: Have you given us the data on all of
25 those batches up through today, because based on our

1 information, [REDACTED]
2 [REDACTED]
3 MR. HALES: Well, my understanding --
4 MS. WACKER: This is Jeanna Wacker.
5 We have produced all data that we have to date.
6 The test dates for the other batches is not coming up until
7 next week, so we don't have any of that.
8 And one other point, Your Honor, I think we need
9 to make is that Eagle is not allowed by the FDA to sell a
10 product [REDACTED] If that were to occur,
11 the products could be recalled. Eagle could be subject to
12 fines. So we're not legally allowed to sell a product that
13 goes outside of our approved specification.
14 THE COURT: All right. Well, I'm not going
15 to make a decision on this today, but I may revisit it
16 May 18th. So we will have a call on May 18th at
17 1:00 o'clock. All right?
18 MR. BLACK: One last thing. The pretrial order,
19 are those dates suspended for submission of the pretrial
20 order?
21 MR. HALES: Your Honor --
22 THE COURT: Go ahead.
23 MR. HALES: I would say we'd like to keep things
24 moving towards trial ready, so from Eagle's perspective, we
25 would like to keep moving on the pretrial order. We could

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1 make some modest adjustments clearly that we aren't going to
2 be going in May, but we would like to move towards trial
3 ready.
4 THE COURT: Actually, you know what I'm going to
5 do, I'm going to keep the pretrial dates. So the only thing
6 I'm postponing right now is the trial. I'm keeping all
7 other dates. All right?
8 MR. BLACK: Okay. Thank you, Your Honor.
9 THE COURT: I think it will help narrow the
10 disputes and will make a more productive call on May 18th.
11 All right. Thanks, everybody. Have a good day.
12 MR. BLACK: Thank you, Your Honor.
13 (Counsel respond, "Thank you, Your Honor.")
14 (Telephone conference concluded at 3:03 p.m.)
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<p>1</p> <p>1 [2] - 16:3, 17:2 10th [2] - 9:22, 11:11 12 [2] - 17:3, 17:5 15 [1] - 17:5 17th [1] - 5:2 18-823-CFC [1] - 1:10 18th [8] - 4:6, 4:23, 5:18, 10:23, 11:14, 22:16, 23:10 1:00 [1] - 22:17</p>	<p>absolutely [1] - 9:25 accept [3] - 20:6, 21:14 accepted [1] - 12:3 accurate [1] - 10:19 ACTION [1] - 1:4 active [1] - 9:4 actual [2] - 17:21, 19:16 addition [1] - 4:13 additional [1] - 14:16 address [1] - 14:24 adjustment [1] - 4:25 adjustments [1] - 23:1 administered [1] - 15:23 advantage [1] - 7:3 afternoon [5] - 3:8, 3:10, 3:15, 3:20, 3:21 agree [5] - 5:25, 7:25, 14:19, 19:8 agreement [1] - 5:13 ahead [1] - 22:22 allowed [2] - 22:9, 22:12 ambiguous [1] - 16:17 amount [2] - 18:25, 19:1 amounts [1] - 15:24 AND [1] - 1:2 ANDA [14] - 6:14, 6:17, 6:24, 12:17, 12:23, 13:1, 13:3, 13:4, 13:15, 14:11, 16:23, 17:1, 18:12, 20:14 ANDERSON [1] - 2:15 Anderson [1] - 3:16 anomalous [2] - 13:23, 20:17 anomaly [5] - 15:9, 18:21, 19:5, 20:5 answer [2] - 15:18, 15:20 APPEARANCES [2] - 1:18, 2:1 application [2] - 5:5, 8:7 approval [27] - 5:3, 5:5, 5:6, 5:13, 7:20, 7:23, 8:5, 8:13, 8:16, 8:18, 8:22, 9:1, 9:3, 9:8, 9:17, 9:25, 10:4, 10:15, 10:20, 10:21, 12:17, 12:21, 13:5, 17:4, 18:14, 18:17 approved [3] - 18:25, 19:1, 22:13 April [1] - 1:13</p>	<p>argue [1] - 13:14 asserted [1] - 12:14 asserting [1] - 12:19 August [1] - 9:7 available [1] - 7:10 aware [1] - 5:4 awful [1] - 7:18</p>	<p>burden [4] - 13:24, 20:15, 20:19, 20:25 BY [5] - 1:19, 2:3, 2:11, 2:16, 2:20</p>	<p>compared [1] - 6:21 compelling [1] - 12:11 competing [1] - 11:5 competitive [1] - 6:11 completed [1] - 21:22 concerned [1] - 4:7 concluded [1] - 23:14 conditions [1] - 20:9 conference [4] - 1:14, 3:5, 11:22, 23:14 CONNOLLY [1] - 1:16 consider [1] - 12:13 contacted [1] - 3:22 context [2] - 18:22, 20:14 Continued [1] - 2:1 contrary [1] - 13:17 control [1] - 13:15 controls [5] - 13:4, 13:13, 18:12, 18:17, 18:25 correct [6] - 11:12, 15:14, 15:15, 15:16, 16:14, 16:20 CORROON [1] - 2:15 counsel [1] - 23:13 Counsel [2] - 2:13, 2:22 couple [1] - 12:2 course [5] - 4:3, 7:21, 9:2, 9:19, 10:24 COURT [33] - 1:1, 3:8, 3:13, 3:19, 3:21, 5:19, 6:2, 6:5, 8:2, 8:14, 8:20, 10:22, 11:13, 11:20, 14:6, 14:23, 15:12, 15:17, 16:6, 16:8, 16:10, 16:15, 16:21, 17:16, 19:4, 19:7, 19:17, 19:20, 19:25, 22:14, 22:22, 23:4, 23:9 Court [9] - 1:24, 5:4, 5:25, 7:10, 7:15, 9:20, 11:24, 12:3, 12:13 Court's [1] - 5:14 courthouse [1] - 4:21 cover [1] - 12:6 covered [1] - 17:19 creative [1] - 5:17 crystal [1] - 7:13 current [2] - 4:7, 4:13</p>
<p>2</p> <p>2020 [1] - 1:13 24 [4] - 17:3, 17:7, 17:9, 18:1 24-month [4] - 16:5, 16:10, 17:4, 20:7 271(a) [1] - 17:15 2:33 [2] - 1:13, 3:6</p>		<p>B</p> <p>ball [1] - 7:13 based [2] - 7:3, 21:25 batch [13] - 14:11, 14:20, 14:25, 15:2, 15:7, 15:8, 15:14, 15:17, 16:18, 17:10, 18:19, 20:7, 21:5 Batch [1] - 16:3 batches [14] - 13:19, 13:21, 14:9, 14:14, 14:17, 15:5, 16:25, 20:23, 21:3, 21:22, 21:25, 22:2, 22:6 Bayer [2] - 18:11, 18:15 BEFORE [1] - 1:16 begin [1] - 3:9 behalf [1] - 5:22 belief [1] - 8:17 believes [1] - 9:24 bench [1] - 11:25 beneficial [1] - 11:7 benefits [1] - 11:2 better [1] - 10:24 between [3] - 10:4, 11:8, 12:15 big [1] - 15:17 BINDU [1] - 2:16 Bindu [1] - 3:16 black [9] - 7:7, 13:17, 15:3, 16:21, 18:9, 18:13, 18:20, 19:8, 21:21 BLACK [13] - 2:11, 4:10, 8:25, 10:9, 14:7, 16:23, 17:21, 19:10, 21:2, 21:24, 22:18, 23:8, 23:12 Black [3] - 3:12, 4:10, 14:7 Black's [1] - 5:23 blessings [1] - 7:11 Bob [1] - 3:12 body [1] - 13:21 brief [1] - 3:25 briefing [1] - 6:8 BRYAN [1] - 2:20 Bryan [5] - 3:17, 5:21, 9:21, 11:17, 18:6 bunch [1] - 9:10</p>	<p>C</p>	
<p>3</p> <p>3 [1] - 17:3 3.4 [6] - 12:18, 12:22, 12:24, 15:11, 18:14, 19:1 3.5 [1] - 21:10 3.6 [10] - 12:18, 12:22, 12:24, 15:11, 17:25, 18:14, 19:1, 19:12, 21:10, 22:10 3.7 [7] - 12:15, 17:25, 19:2, 19:14, 20:11, 21:10, 21:12 3.8 [4] - 12:16, 13:20, 18:19, 21:12 3.9 [2] - 12:15, 19:2 30-month [4] - 5:1, 5:6, 5:12, 6:10 3:03 [1] - 23:14</p>			<p>calendar [1] - 8:4 California [1] - 4:19 cancel [1] - 10:23 carry [4] - 13:24, 20:15, 20:19, 20:25 case [18] - 5:2, 9:12, 10:6, 12:5, 12:8, 12:20, 12:25, 13:7, 13:8, 13:11, 13:13, 14:1, 16:24, 18:8, 18:11, 18:12, 18:15, 20:13 cases [5] - 18:21, 20:5, 20:12, 20:18 certain [1] - 15:24 challenges [1] - 6:18 chambers [1] - 3:23 characterizing [1] - 21:5 Circuit [3] - 13:22, 18:11, 20:12 circumstance [1] - 4:5 circumstances [3] - 4:7, 7:6, 14:2 CIVIL [1] - 1:4 claim [1] - 13:2 claimed [2] - 18:25, 19:2 claims [1] - 12:19 clarification [1] - 10:10 clean [1] - 13:6 clear [6] - 3:24, 6:18, 7:11, 12:25, 13:21, 18:16 clearly [4] - 18:13, 18:19, 20:6, 23:1 client [6] - 7:16, 7:22, 8:19, 9:24, 10:15, 14:25 close [1] - 4:2 co [1] - 5:9 co-defendants [1] - 5:9 COLM [1] - 1:16 coming [2] - 8:24, 22:6 commenced [1] - 3:5 comment [1] - 10:7 commercial [2] - 9:13 company [3] - 6:16, 6:23, 7:18 COMPANY [1] - 1:6</p>	
<p>6</p>				
<p>6 [1] - 17:3</p>				
<p>8</p>				
<p>8 [1] - 1:13</p>				
<p>9</p>				
<p>9 [1] - 17:3</p>				
<p>A</p>				
<p>ability [1] - 6:23 able [1] - 12:22</p>				<p>D</p> <p>Dan [1] - 3:12 DANIEL [1] - 2:7 data [21] - 8:9, 13:16, 13:18, 13:19, 14:16,</p>

14:18, 15:9, 17:1, 17:8, 19:3, 20:8, 20:11, 20:17, 20:18, 20:21, 21:4, 21:21, 21:24, 22:1, 22:5 date [6] - 4:8, 5:17, 7:9, 8:22, 9:22, 22:5 dates [4] - 22:6, 22:19, 23:5, 23:7 deal [1] - 5:12 dealing [1] - 4:1 DECHERT [3] - 2:3, 2:6, 2:10 Dechert [1] - 3:12 decided [1] - 3:25 decision [2] - 10:5, 22:15 defendant [2] - 5:3, 11:10 Defendant [2] - 1:10, 2:22 defendants [5] - 5:9, 5:19, 8:15, 9:10, 11:23 defense [1] - 3:14 defenses [1] - 9:10 DELAWARE [1] - 1:2 Delaware [6] - 1:12, 4:14, 4:15, 4:17, 4:21, 4:22 detail [1] - 21:8 differences [1] - 6:22 different [2] - 13:4, 20:8 difficult [2] - 11:1, 11:2 disagree [3] - 18:3, 18:13, 19:11 dispose [1] - 14:1 dispositive [1] - 12:9 dispute [4] - 19:9, 19:11, 19:22, 21:17 disputes [1] - 23:10 DISTRICT [2] - 1:1, 1:2 doable [1] - 4:8 docketing [1] - 9:14 DOE [1] - 12:20 done [6] - 15:5, 15:13, 16:4, 16:18, 20:23 down [1] - 20:9 dropped [1] - 12:7 drug [1] - 12:18 drugs [1] - 15:22 during [1] - 15:22	22:11 EAGLE [1] - 1:9 Eagle's [3] - 6:10, 12:17, 22:24 early [3] - 8:7, 8:18, 11:21 eat [1] - 7:2 effort [1] - 6:17 elegant [1] - 5:10 ELLIS [1] - 2:19 Ellis [1] - 3:18 end [2] - 13:13, 15:6 ENDO [1] - 1:5 ends [1] - 17:21 enormous [1] - 9:12 enters [1] - 4:15 entire [1] - 12:5 entities [1] - 7:4 equities [1] - 11:5 ESQ [7] - 1:19, 2:3, 2:7, 2:11, 2:16, 2:20, 2:20 establishing [1] - 20:15 event [1] - 4:4 evidence [3] - 14:20, 17:12, 18:2 example [1] - 19:16 except [2] - 5:5, 17:18 exclusivity [5] - 6:14, 6:16, 6:20, 7:2, 7:17 exists [1] - 18:21 expect [1] - 8:15 expectation [2] - 7:21, 18:23 expected [2] - 8:21, 20:4 expecting [2] - 7:22, 10:10 expects [1] - 11:10 expend [1] - 9:11 expert [4] - 4:19, 18:2, 20:2, 21:6 expert's [3] - 21:14, 21:17, 21:18 experts [4] - 17:8, 18:2, 19:11, 19:22 expiration [1] - 6:9 expires [1] - 5:2 extension [1] - 4:13	falls [4] - 14:25, 17:13, 17:17, 17:18 Farnan [2] - 3:11, 4:11 FARNAN [3] - 1:19, 1:19, 3:10 fast [1] - 6:8 FDA [13] - 5:4, 8:5, 8:12, 9:4, 9:23, 10:11, 10:16, 14:12, 14:15, 17:8, 17:17, 21:4, 22:9 FDA's [1] - 10:1 Federal [3] - 13:22, 18:11, 20:12 fell [1] - 14:10 Ferring [1] - 20:13 few [2] - 4:18, 6:15 figure [2] - 7:8, 9:18 filed [1] - 8:6 filer [1] - 6:13 filers [1] - 6:14 filing [1] - 11:23 final [1] - 5:8 finally [2] - 7:19 finer [1] - 22:12 first [8] - 6:13, 6:17, 10:7, 11:3, 11:14, 11:21, 13:20, 14:24 five [2] - 5:9, 20:18 following [1] - 3:5 FOR [1] - 1:2 forever [1] - 9:1 form [1] - 9:19 forward [1] - 13:11 fourth [2] - 16:4, 16:11 frankly [1] - 6:16	21:20, 22:3, 22:21, 22:23 Hales [8] - 3:17, 5:22, 9:21, 10:14, 11:17, 14:24, 18:6, 19:18 hands [1] - 10:1 happy [1] - 6:6 hard [1] - 14:12 head [1] - 15:20 heard [4] - 12:1, 12:2, 21:15 help [1] - 23:9 hold [1] - 19:7 honest [1] - 8:23 Honor [31] - 3:10, 3:15, 3:20, 4:10, 5:1, 5:21, 6:7, 7:19, 8:4, 8:17, 8:23, 9:6, 9:14, 9:21, 10:7, 11:12, 11:17, 14:4, 14:7, 15:2, 15:19, 16:23, 18:6, 19:6, 19:24, 21:20, 22:8, 22:21, 23:8, 23:12, 23:13 HONORABLE [1] - 1:16 hope [1] - 12:12 hopefully [2] - 5:13, 11:15 hoping [1] - 10:15 hospital [1] - 4:20 hundred [2] - 15:4, 20:19 hundreds [8] - 13:16, 13:18, 15:9, 17:1, 20:8, 20:10, 20:24, 21:2	initial [1] - 15:21 INNOVATION [1] - 1:5 instance [1] - 11:9 interests [1] - 6:12 interrupt [1] - 16:8 invested [2] - 6:16, 7:18 investment [2] - 6:24, 7:3 investment-based [1] - 7:3 involved [1] - 10:6 issue [7] - 5:8, 9:15, 12:6, 12:8, 12:9, 13:6, 16:22 issues [5] - 9:13, 9:14, 13:25, 14:5
J				
January [7] - 5:10, 5:11, 5:23, 6:22, 7:2, 7:25, 9:10 JEANNA [1] - 2:20 Jeanna [2] - 3:17, 22:4 Jersey [2] - 2:4, 2:7 judgment [8] - 11:24, 12:4, 12:8, 18:5, 19:21, 19:23, 21:15, 21:17 July [2] - 7:12, 9:7 June [1] - 7:12				
K				
keep [5] - 4:1, 13:11, 22:23, 22:25, 23:5 keeping [1] - 23:6 kind [2] - 10:5, 19:9 kindly [2] - 6:8, 12:1 KIRKLAND [1] - 2:19 Kirkland [1] - 3:17 knows [3] - 5:1, 9:2, 9:4				
L				
Labs [1] - 20:13 largely [1] - 13:4 last [10] - 5:24, 6:1, 6:3, 6:8, 8:21, 8:24, 9:23, 10:11, 16:11, 22:18 latest [1] - 8:19 law [8] - 4:14, 4:22, 12:25, 13:12, 13:22, 15:9, 20:20, 21:1 left [2] - 13:8, 13:15 legal [2] - 13:6, 13:25 legally [1] - 22:12				

<p>letting [1] - 12:13</p> <p>level [2] - 12:15, 17:24</p> <p>life [7] - 12:24, 15:7, 15:22, 16:5, 16:10, 17:22, 18:20</p> <p>light [1] - 12:12</p> <p>likelihood [1] - 4:13</p> <p>likely [5] - 7:6, 10:16, 19:13, 20:16, 21:9</p> <p>line [4] - 3:11, 3:16, 18:21, 20:5</p> <p>literal [2] - 12:20, 15:6</p> <p>literally [2] - 13:23, 16:4</p> <p>live [1] - 4:18</p> <p>LLC [2] - 1:5, 1:6</p> <p>LLP [6] - 1:19, 2:3, 2:6, 2:10, 2:15, 2:19</p> <p>lock [1] - 9:7</p> <p>logistical [1] - 7:3</p> <p>lone [1] - 20:6</p> <p>look [3] - 6:2, 17:2</p> <p>looking [1] - 20:14</p> <p>looks [1] - 11:4</p>	<p>17:3, 22:1</p> <p>months [8] - 16:1, 17:3, 17:5, 17:7, 17:9, 18:1, 21:3</p> <p>morning [1] - 3:23</p> <p>most [1] - 22:1</p> <p>motion [4] - 11:23, 12:4, 14:3, 21:15</p> <p>move [6] - 5:11, 5:23, 11:2, 19:15, 20:1, 23:2</p> <p>moves [2] - 17:25, 19:13</p> <p>moving [3] - 7:1, 22:24, 22:25</p> <p>MR [40] - 3:10, 3:20, 4:10, 5:21, 6:4, 6:7, 8:3, 8:17, 8:23, 8:25, 9:21, 10:9, 11:12, 11:17, 11:21, 14:7, 15:2, 15:15, 15:18, 16:7, 16:9, 16:14, 16:20, 16:23, 17:21, 18:6, 19:5, 19:10, 19:19, 19:24, 20:4, 21:2, 21:20, 21:24, 22:3, 22:18, 22:21, 22:23, 23:8, 23:12</p> <p>MS [2] - 3:15, 22:4</p> <p>multiple [1] - 15:13</p>	<p>22:17</p> <p>obtained [1] - 5:12</p> <p>obviously [4] - 7:13, 8:3, 15:19, 16:24</p> <p>occur [1] - 22:10</p> <p>October [2] - 5:2, 6:9</p> <p>odd [2] - 7:5, 8:4</p> <p>oddly [1] - 5:2</p> <p>OF [1] - 1:2</p> <p>Official [1] - 1:24</p> <p>one [38] - 4:2, 5:10, 5:24, 6:13, 6:17, 9:16, 11:18, 11:22, 11:25, 12:2, 13:6, 13:19, 13:20, 13:23, 14:9, 15:4, 15:5, 15:6, 15:8, 15:13, 15:25, 16:4, 16:18, 18:9, 18:10, 18:13, 19:5, 19:15, 20:6, 20:7, 20:10, 20:24, 21:3, 22:8, 22:18</p> <p>one-hundred-and-some [1] - 15:4</p> <p>one-tenth [1] - 19:15</p> <p>opinion [1] - 21:18</p> <p>order [3] - 22:18, 22:20, 22:25</p> <p>original [3] - 11:14, 14:9, 15:7</p> <p>outlier [1] - 13:23</p> <p>outlined [1] - 7:7</p> <p>outset [1] - 16:16</p> <p>outside [3] - 12:18, 14:25, 22:13</p> <p>owner [1] - 20:15</p>	<p>12:7, 12:14, 21:13</p> <p>Pennsylvania [1] - 2:11</p> <p>period [1] - 17:22</p> <p>periodically [1] - 15:25</p> <p>periods [1] - 20:24</p> <p>permission [1] - 14:3</p> <p>perspective [3] - 6:11, 9:16, 22:24</p> <p>pH [17] - 12:15, 12:18, 12:23, 14:10, 15:8, 15:10, 15:21, 15:23, 16:1, 16:2, 16:4, 17:10, 18:23, 19:13, 20:8, 20:11, 22:10</p> <p>PHARMACEUTICAL [2] - 1:4, 1:9</p> <p>Philadelphia [2] - 2:11, 4:18</p> <p>phone [2] - 8:21, 10:25</p> <p>PI [1] - 5:14</p> <p>pick [1] - 7:9</p> <p>plaintiff [2] - 3:11, 14:8</p> <p>Plaintiffs [2] - 1:7, 2:13</p> <p>plaintiffs [3] - 3:9, 4:9, 14:6</p> <p>plan [1] - 10:24</p> <p>planning [1] - 21:7</p> <p>play [1] - 7:23</p> <p>plays [1] - 7:24</p> <p>point [13] - 9:6, 10:2, 13:8, 13:9, 13:20, 14:24, 15:6, 15:8, 15:23, 18:18, 19:5, 20:17, 22:8</p> <p>points [10] - 13:16, 13:18, 13:23, 15:9, 17:1, 20:8, 20:11, 20:18, 20:21, 21:4</p> <p>position [1] - 4:9</p> <p>possibility [1] - 11:23</p> <p>possible [2] - 10:24, 11:8</p> <p>postponing [1] - 23:6</p> <p>POTTER [1] - 2:15</p> <p>Potter [1] - 3:16</p> <p>premature [1] - 5:7</p> <p>prepare [1] - 4:17</p> <p>present [1] - 14:3</p> <p>pretrial [4] - 22:18, 22:19, 22:25, 23:5</p> <p>Princeton [1] - 2:4</p> <p>princeton [1] - 2:7</p> <p>problems [1] - 8:8</p> <p>proceed [2] - 7:11, 12:4</p>	<p>proceedings [1] - 4:3</p> <p>process [1] - 18:24</p> <p>produced [3] - 8:10, 13:17, 22:5</p> <p>product [24] - 6:25, 12:18, 12:22, 14:13, 16:12, 16:13, 16:24, 17:4, 17:5, 17:11, 17:13, 17:21, 17:24, 18:10, 18:14, 18:18, 19:12, 19:14, 19:21, 21:7, 21:9, 21:12, 22:10, 22:12</p> <p>productive [1] - 23:10</p> <p>PRODUCTS [1] - 1:5</p> <p>products [2] - 15:21, 22:11</p> <p>proposal [1] - 11:19</p> <p>proposed [2] - 6:14, 12:17</p> <p>proposing [1] - 12:5</p> <p>protect [2] - 6:23, 7:17</p> <p>public [2] - 4:4, 17:12</p> <p>purposes [2] - 19:20, 21:15</p> <p>put [3] - 6:8, 6:24, 17:17</p>
M				Q
<p>mail [1] - 3:23</p> <p>map [1] - 20:10</p> <p>mark [1] - 20:7</p> <p>market [8] - 11:3, 16:24, 17:18, 18:10, 18:14, 21:10, 21:11</p> <p>MARTIN [1] - 2:11</p> <p>Martin [3] - 3:12, 4:10, 14:7</p> <p>massive [1] - 10:12</p> <p>matter [3] - 16:17, 20:20, 21:1</p> <p>mean [3] - 7:13, 10:2, 19:21</p> <p>measured [1] - 15:23</p> <p>measurement [7] - 15:6, 15:8, 15:10, 16:2, 16:11, 20:7, 20:25</p> <p>measurements [2] - 15:13, 20:8</p> <p>MICHAEL [1] - 1:19</p> <p>Michael [1] - 3:11</p> <p>miles [1] - 4:18</p> <p>mindful [1] - 11:2</p> <p>minutes [1] - 12:2</p> <p>modest [1] - 23:1</p> <p>moment [2] - 6:19, 11:18</p> <p>monitoring [2] - 15:5, 15:25</p> <p>month [8] - 7:23, 9:17, 10:16, 16:5, 16:12,</p>	<p>N</p> <p>name [1] - 18:8</p> <p>narrow [1] - 23:9</p> <p>need [3] - 4:24, 17:3, 22:8</p> <p>new [1] - 14:14</p> <p>New [4] - 2:4, 2:7, 2:21</p> <p>next [2] - 5:11, 22:7</p> <p>nine [3] - 16:1, 21:22, 22:1</p> <p>nine-month [1] - 22:1</p> <p>NO [1] - 1:10</p> <p>nobody [3] - 7:13, 8:12, 9:1</p> <p>noninfringement [2] - 12:9, 14:4</p> <p>normal [2] - 4:3, 9:2</p> <p>normally [2] - 8:6, 11:24</p> <p>nothing [1] - 7:24</p> <p>nub [2] - 19:9, 19:10</p> <p>Number [1] - 16:3</p> <p>number [2] - 13:23, 20:21</p>			<p>qualified [1] - 21:18</p> <p>quarantine [2] - 4:15, 4:23</p> <p>quick [2] - 12:13, 18:7</p>
		P		R
<p>mail [1] - 3:23</p> <p>map [1] - 20:10</p> <p>mark [1] - 20:7</p> <p>market [8] - 11:3, 16:24, 17:18, 18:10, 18:14, 21:10, 21:11</p> <p>MARTIN [1] - 2:11</p> <p>Martin [3] - 3:12, 4:10, 14:7</p> <p>massive [1] - 10:12</p> <p>matter [3] - 16:17, 20:20, 21:1</p> <p>mean [3] - 7:13, 10:2, 19:21</p> <p>measured [1] - 15:23</p> <p>measurement [7] - 15:6, 15:8, 15:10, 16:2, 16:11, 20:7, 20:25</p> <p>measurements [2] - 15:13, 20:8</p> <p>MICHAEL [1] - 1:19</p> <p>Michael [1] - 3:11</p> <p>miles [1] - 4:18</p> <p>mindful [1] - 11:2</p> <p>minutes [1] - 12:2</p> <p>modest [1] - 23:1</p> <p>moment [2] - 6:19, 11:18</p> <p>monitoring [2] - 15:5, 15:25</p> <p>month [8] - 7:23, 9:17, 10:16, 16:5, 16:12,</p>	<p>O</p> <p>o'clock [2] - 1:13,</p>	<p>p.m [3] - 1:13, 3:6, 23:14</p> <p>PALAPURA [2] - 2:16, 3:15</p> <p>Palapura [1] - 3:16</p> <p>pandemic [1] - 9:14</p> <p>papers [1] - 5:14</p> <p>Par [6] - 12:7, 12:19, 13:9, 13:10, 13:13, 18:22</p> <p>PAR [3] - 1:4, 1:5, 1:5</p> <p>participate [1] - 3:24</p> <p>particular [5] - 6:24, 10:11, 10:17, 16:18, 17:24</p> <p>particularly [1] - 14:1</p> <p>parties [2] - 3:22, 4:2</p> <p>past [1] - 18:20</p> <p>patent [4] - 9:9, 14:21, 17:20, 20:14</p> <p>patents [5] - 5:9, 12:6,</p>	<p>raise [1] - 11:18</p> <p>raised [2] - 5:24, 11:22</p> <p>range [13] - 12:16, 12:19, 12:23, 14:10, 14:25, 15:11, 17:10, 17:18, 17:19, 17:22, 19:1, 19:2, 21:5</p> <p>read [1] - 16:1</p> <p>ready [3] - 5:5, 22:24, 23:3</p> <p>real [1] - 18:3</p> <p>really [5] - 4:8, 4:12, 6:11, 7:15, 7:16</p> <p>reasonably [1] - 7:9</p> <p>reasons [3] - 12:1, 12:3, 18:11</p> <p>recalled [1] - 22:11</p> <p>recent [1] - 22:2</p> <p>recognizing [1] - 7:5</p> <p>recollection [1] - 6:2</p> <p>reference [1] - 10:2</p> <p>referring [1] - 15:3</p>	

reformulate [1] - 14:13 refrigerated [1] - 20:9 refused [1] - 14:18 regardless [1] - 5:14 registration [1] - 15:7 Registration [1] - 16:3 regroup [1] - 9:18 relation [1] - 11:19 release [3] - 12:23, 15:4, 15:23 remaining [1] - 12:14 Reporter [1] - 1:24 represent [1] - 10:19 request [2] - 7:8, 14:3 requests [1] - 12:17 required [1] - 13:3 requirement [1] - 12:15 requires [1] - 13:3 resolve [3] - 12:5, 13:7 resolves [1] - 13:1 respect [1] - 21:20 respond [3] - 9:23, 10:17, 23:13 response [4] - 10:10, 10:13, 10:17, 11:11 retry [1] - 9:9 revisit [4] - 10:20, 10:25, 11:16, 22:15 RHOAD [1] - 2:3 Rhoad [1] - 3:12 ripe [1] - 18:4 rise [1] - 18:25 rises [1] - 22:10 ROBERT [1] - 2:3 Roberts [1] - 3:12 ROBERTS [1] - 2:7 room [1] - 20:9 running [1] - 8:10	14:11, 14:21, 15:1, 16:12, 17:21, 17:24, 17:25, 18:15, 18:19, 19:11, 22:9, 22:12 selling [1] - 17:13 sense [2] - 8:4, 9:15 September [1] - 11:8 set [2] - 9:7, 19:3 shelf [5] - 12:23, 15:7, 15:22, 16:5, 16:10 significance [1] - 6:9 similarly [1] - 17:15 single [4] - 13:19, 16:2, 20:24 situation [3] - 4:14, 7:24, 12:12 situations [1] - 11:25 six [3] - 12:6, 15:25, 22:1 six-month [1] - 22:1 sixty [1] - 12:10 small [2] - 13:23, 20:20 snuck [1] - 21:13 sold [1] - 18:18 solution [1] - 5:10 sometimes [1] - 10:4 somewhat [2] - 5:2, 5:10 soon [1] - 7:9 sorry [5] - 7:19, 16:8, 19:6, 19:18, 19:24 sort [1] - 18:4 spec [6] - 13:4, 13:13, 13:15, 13:20, 17:14, 17:17 specific [1] - 17:10 specifically [1] - 12:16 specification [9] - 13:1, 13:3, 13:16, 15:11, 16:3, 18:12, 18:16, 18:24, 22:13 specified [1] - 12:18 stability [6] - 8:9, 13:18, 13:19, 14:16, 15:4, 15:24 stage [1] - 8:6 state [1] - 4:15 STATES [1] - 1:1 status [2] - 5:15, 17:2 statutory [4] - 6:13, 6:16, 6:20, 7:2 stay [4] - 5:1, 5:6, 5:12, 6:10 STERILE [1] - 1:5 still [3] - 5:6, 5:25, 10:3 stipulate [2] - 19:20, 20:2 stop [1] - 19:17	story [1] - 12:14 structure [1] - 10:6 stuff [1] - 11:2 subject [1] - 22:11 submission [3] - 9:23, 10:11, 22:19 submitted [5] - 14:14, 14:16, 17:1, 17:8, 21:4 suggestion [1] - 5:23 sum [1] - 9:12 summary [8] - 11:24, 12:4, 12:8, 18:4, 19:21, 19:23, 21:15, 21:16 supposed [1] - 9:23 suspended [1] - 22:19	throw [1] - 18:7 today [3] - 3:17, 21:25, 22:15 top [1] - 15:20 touch [1] - 7:21 towards [2] - 22:24, 23:2 trial [22] - 4:6, 5:8, 5:11, 5:17, 6:21, 6:22, 7:7, 7:25, 8:15, 9:7, 9:18, 10:5, 10:23, 11:4, 11:8, 11:15, 11:25, 14:3, 21:19, 22:24, 23:2, 23:6 trials [1] - 10:3 true [1] - 18:9 try [4] - 7:8, 7:16, 7:17, 18:22 trying [3] - 5:17, 9:12, 19:25 twelve [1] - 16:1 twenty [2] - 16:4, 16:11 twenty-fourth [2] - 16:4, 16:11 twice [1] - 9:12 two [6] - 4:16, 6:11, 13:11, 13:25, 14:4, 18:7 type [1] - 4:3	W WACKER [2] - 2:20, 22:4 Wacker [2] - 3:17, 22:4 wait [2] - 9:16, 14:23 waiting [1] - 10:3 Watson [1] - 20:13 Wednesday [1] - 1:13 week [1] - 22:7 weeks [1] - 4:16 willing [1] - 20:2 Wilmington [1] - 1:12 win [1] - 13:12 works [1] - 9:19 world [2] - 4:8, 18:3 wrap [1] - 20:1
S saleable [1] - 17:6 sample [1] - 16:25 schedule [2] - 6:8, 11:8 scheduled [3] - 4:6, 5:9, 11:4 scheduling [4] - 4:1, 9:14, 10:7, 11:22 second [2] - 13:9, 18:18 seconds [1] - 12:10 see [5] - 5:17, 10:23, 11:9, 19:22, 21:16 seeking [1] - 18:16 seem [1] - 7:6 sell [14] - 12:22, 13:5,	14:11, 14:21, 15:1, 16:12, 17:21, 17:24, 17:25, 18:15, 18:19, 19:11, 22:9, 22:12 selling [1] - 17:13 sense [2] - 8:4, 9:15 September [1] - 11:8 set [2] - 9:7, 19:3 shelf [5] - 12:23, 15:7, 15:22, 16:5, 16:10 significance [1] - 6:9 similarly [1] - 17:15 single [4] - 13:19, 16:2, 20:24 situation [3] - 4:14, 7:24, 12:12 situations [1] - 11:25 six [3] - 12:6, 15:25, 22:1 six-month [1] - 22:1 sixty [1] - 12:10 small [2] - 13:23, 20:20 snuck [1] - 21:13 sold [1] - 18:18 solution [1] - 5:10 sometimes [1] - 10:4 somewhat [2] - 5:2, 5:10 soon [1] - 7:9 sorry [5] - 7:19, 16:8, 19:6, 19:18, 19:24 sort [1] - 18:4 spec [6] - 13:4, 13:13, 13:15, 13:20, 17:14, 17:17 specific [1] - 17:10 specifically [1] - 12:16 specification [9] - 13:1, 13:3, 13:16, 15:11, 16:3, 18:12, 18:16, 18:24, 22:13 specified [1] - 12:18 stability [6] - 8:9, 13:18, 13:19, 14:16, 15:4, 15:24 stage [1] - 8:6 state [1] - 4:15 STATES [1] - 1:1 status [2] - 5:15, 17:2 statutory [4] - 6:13, 6:16, 6:20, 7:2 stay [4] - 5:1, 5:6, 5:12, 6:10 STERILE [1] - 1:5 still [3] - 5:6, 5:25, 10:3 stipulate [2] - 19:20, 20:2 stop [1] - 19:17	T telephone [3] - 3:5, 4:4, 23:14 Telephone [1] - 1:14 temperature [1] - 20:10 tentative [6] - 5:3, 5:4, 7:20, 7:23, 9:17, 10:4 tenth [1] - 19:15 terms [1] - 6:23 test [4] - 13:18, 15:5, 16:7, 22:6 tested [3] - 14:17, 15:11, 21:3 testimony [1] - 21:14 testing [1] - 15:24 tests [6] - 8:10, 14:14, 15:4, 16:4, 20:22, 21:22 THE [34] - 1:1, 1:2, 3:8, 3:13, 3:19, 3:21, 5:19, 6:2, 6:5, 8:2, 8:14, 8:20, 10:22, 11:13, 11:20, 14:6, 14:23, 15:12, 15:17, 16:6, 16:8, 16:10, 16:15, 16:21, 17:16, 19:4, 19:7, 19:17, 19:20, 19:25, 22:14, 22:22, 23:4, 23:9 theoretical [1] - 18:23 therefore [1] - 14:20 they've [2] - 8:25, 14:13 thinks [1] - 10:14 thoughts [2] - 5:16, 18:7 three [7] - 12:7, 12:14, 14:9, 15:25, 16:25, 21:2, 21:3	U U.S.D.C.J [1] - 1:16 uncertainty [1] - 14:2 under [2] - 14:11, 17:15 understood [1] - 9:24 underway [1] - 21:22 UNITED [1] - 1:1 unlikely [1] - 4:23 unstable [1] - 14:13 up [12] - 4:18, 7:2, 8:24, 17:3, 17:22, 18:25, 19:1, 20:1, 20:5, 20:11, 21:25, 22:6 upright [1] - 20:9 upside [1] - 20:9 urgency [1] - 8:5	Y York [2] - 2:21
V Valerie [1] - 1:24 validity [1] - 9:9 variety [1] - 21:23 versus [1] - 20:13 violating [1] - 4:22 vs [1] - 1:8				

EXHIBIT B

IN THE UNITED STATES DISTRICT COURT

IN AND FOR THE DISTRICT OF DELAWARE

4 PAR PHARMACEUTICAL, INC., : CIVIL ACTION
5 PAR STERILE PRODUCTS, LLC, :
and ENDO PAR INNOVATION :
6 COMPANY, LLC, :
:
7 Plaintiffs, :
:
8 vs. :
:
9 EAGLE PHARMACEUTICAL INC., :
:
10 Defendant. : NO. 18-823-CFC

L3 Wilmington, Delaware
Monday, May 18, 2020
1:00 o'clock, p.m.
L4 ***Telephone conference

16 BEFORE: HONORABLE COLM F. CONNOLLY, U.S.D.C.J.

18 **APPEARANCES:**

24 Valerie J. Gunning
Official Court Reporter

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19 Counsel for Defendant

20 - - -

1 MR. HALES: Hello, your Honor. This is Bryan
2 Hales from Kirkland, and let me take that.

3 The answer to that is, no, we can't sell
4 something that's not in compliance with our specification.
5 All right. We've only sought approval for something that is
6 within the spec on release and through stability. So if we
7 learned of that during the shelf life, then I think the
8 answer to that is no, because we wouldn't have approval for
9 that.

10 THE COURT: Okay. Because you said in a
11 hearing -- I went back and looked at the transcript. You
12 said they couldn't sell it. But what I guess I'm confused
13 by is, you know, Par has put in the record the regs, and it
14 looks like to me that you could sell it if it didn't -- or
15 you could seek an exception and you could continue to sell
16 it.

17 MR. HALES: I think the regs -- well, I am not
18 an FDA regulatory expert, Your Honor, but what I think
19 that's contemplating, and when you have a field action is
20 when you learn about something that was in the field.
21 Right? And let's say it's already out there and then you
22 learn something has gone wrong.

23 THE COURT: Right.

24 MR. HALES: It seems to me a different scenario.

25 THE COURT: Well, when you say scenario, that's

3

1 P R O C E E D I N G S

2
3 (The following telephone conference was held
4 beginning at 1:00 p.m.)

5
6 THE COURT: All right. Good afternoon. Let's
7 hear from plaintiffs, please.

8 MR. FARNAN: Good afternoon, Your Honor. Brian
9 Farnan on behalf of the plaintiff, and with me is Martin
10 Black, Robert Rhoad and Brian Goldberg, all from Dechert.
11 We also have Lawrence Brown from Par on the phone.

12 THE COURT: All right. Thank you. And then
13 let's hear from Eagle.

14 MS. PALAPURA: Good afternoon, Your Honor.
15 Bindu Palapu from Potter Anderson on behalf of defendant
16 Eagle. With me today from Potter Anderson is my colleague,
17 David Moore. Also with me today is Bryan Hales and Jeanna
18 Wacker from Kirkland & Ellis.

19 THE COURT: Okay. Great.

20 All right. Thank you, all. I've read the
21 papers as far as the request for summary judgment.

22 Let me just ask Eagle a question. Can Eagle
23 sell the product, its ANDA product, if the pH is measured at
24 some point during the shelf life of the product to fall
25 within the range covered by the patent?

5

1 what I'm trying to figure out, is it seems to me that this
2 is really what the whole issue turns on, is if you fail to
3 meet the stability spec because the pH level is within the
4 range but you can then go ahead and sell it seeking an
5 exception to, under these field reports, it just strikes me
6 that it's not enough then to say that just because you
7 failed to meet the spec, that you're not going to infringe,
8 that you are not going to have a product out there.

9 MR. HALES: I guess the response is, what I
10 think I was trying to say is, if we learned about it before
11 the product was sold, then we wouldn't have authorization to
12 sell it, right, because we have not sought approval for
13 that, and the idea that we would try to get an exception to
14 change it I think is speculative. There's no evidence that
15 that would happen.

16 The field report issues come up when something
17 unexpected happens that was already in the field, and in
18 those scenarios if all you were concerned about is patient
19 safety, let's say there was no patent litigation issue, then
20 it might be that somebody says, we learned something
21 different than expected or different than was approved in
22 the field, that's already out there, and they investigated
23 this as standard stuff for generics, they would investigate,
24 FDA or anybody approved, they would investigate it, why did
25 it happen, and is there a patient safety issue and take

1 action.

2 Here you would have a scenario where clearly
3 there would be -- and, again, this is speculating on things
4 that haven't happened, but there would be legal input as
5 well because the ramifications on patient safety are one
6 thing and the ramifications in terms of what Par might
7 allege are a different thing.

8 So I just think it's too speculative to suggest
9 that we shouldn't have this issue considered now because of
10 those things that might happen, because all of that theory
11 rests, Your Honor, on the premise that Eagle is not going
12 to comply with its spec, and the Federal Circuit cases say
13 that when we're in the ANDA setting, which is where we are,
14 we have no commercial product on the market, Par can't
15 presume that there's going to be noncompliance with the
16 spec.

17 THE COURT: No, but there's a difference, it
18 seems to me, between the cases. I mean, I actually don't
19 think you -- well, I don't think you have fairly summarized
20 the cases in their totality. I think you have taken
21 language out of the Elan case and then you've ignored
22 essentially the holdings of the subsequent cases.

23 So, yes, I think the Federal Circuit has clearly
24 said we're going to presume that there's compliance with the
25 ANDA, but they've said you can look to extrinsic factors,

7

1 and they took comfort in Elan because there was no
2 suggestion by anybody that the ANDA wasn't going to be
3 complied with and would not lead to sales. The difference
4 is you've gotten -- and then in the other cases where
5 they've got a product on the market, it's a different
6 question.

7 That is what we have here, is we've got a
8 product that, it seems to me there's a factual dispute, we
9 can get to that in a second, over whether or not the
10 stability -- [REDACTED]
11 [REDACTED]
12 [REDACTED], and you are asking me to take comfort in the
13 fact that, yes, but we're not going to sell it if we know
14 about that. But this is not something that every day before
15 the product is sold there's a test run. And so as I
16 understand it, there's some kind of, I don't know if it's
17 random or some periodic testing, and if that testing reveals
18 that you've got product that does not comport with the spec,
19 you're still not precluded necessarily, as I understand it,
20 from selling the product. You would have to at that point
21 get into some kind of safety determination.

22 I mean, is that not a fair summary, at least the
23 last part, that it is not a mandated removal from the
24 market, but instead there would be some kind of safety
25 considerations to determine whether or not the product could

1 be continued to be sold?

2 MR. HALES: Well, again, I have to say, Your
3 Honor, I'm not a regulatory expert to be sure, but I do
4 think again there's a difference. Right?

5 We are seeking approval, Eagle is seeking
6 approval to sell a product that has a pH spec on release and
7 maintained through shelf life, so if we learned that it was
8 not maintaining before it went out the door, I don't think
9 we could sell that, because we don't have approval to sell
10 that.

11 THE COURT: And I think if you could guarantee
12 me that the thing never got -- never got to the market,
13 that's one thing, but I don't think you can do that, it
14 sounds.

15 MR. HALES: Well, I think this is the point of
16 the cases that say we don't make those presumptions though.
17 I mean, I can't sit here today, but if we disagree with
18 Par's assertion that there's going to be this [REDACTED] all
19 right, clearly, but we're on summary judgment, so I
20 understand the context.

21 I can't guarantee in the context of summary
22 judgment for sure that that hypothesis would never happen,
23 but I think we are being fair about the cases, because if
24 you look at the In re Brimonidine case, it's a very, very
25 analogous situation to this one where the claims required a

9

1 pH above seven. The ANDA specification required 6.5 to 6.7.
2 The parties in that case agreed that pH would drift down
3 over time, and so the plaintiff hypothesized that in order
4 to never go below 6.5 during shelf life, which is what the
5 ANDA spec said, the product would have to begin above .7,
6 which would be out of spec and within the claims and
7 therefore there was infringement.

8 And the Federal Circuit said, no, we cannot
9 make that presumption that they're going to release out of
10 spec.

11 The --

12 THE COURT: But I mean let me just -- sorry to
13 interrupt. I mean, isn't release a different story, because
14 there the FDA is involved and you are not worried about
15 there being a sale, I mean, as opposed to something that is
16 passive. In other words, when you are doing the release,
17 right, your client is actively making the product, has to
18 ensure compliance before it leaves the factory, but once you
19 put it on the shelf, there's not that kind of active
20 insurance that if, in fact, the [REDACTED], it's not going to
21 be sold and sold as an infringing product.

22 MR. HALES: But I think that's the same as
23 Brimonidine, because the argument in Brimonidine is that in
24 order for it to stay in spec throughout its life, it would
25 necessarily have to begin out of spec in an infringing

1 scenario. And the Federal Circuit said you can't make that
2 presumption, and the District Court said, you know, actually
3 found infringement, and the Federal Circuit said, no, you
4 can't make that presumption.

5 What Par is doing is the same. They are
6 accepting for this purpose that we're releasing the spec,
7 but then they are presuming [REDACTED]

8 [REDACTED] That would be contrary to what we sought
9 approval for. The FDA is not going to give us approval
10 unless they are satisfied that they've got data that shows
11 we're going to maintain our spec, which is a release and
12 stability through shelf life specification.

13 THE COURT: I think the difference though is
14 that, I don't think there's any question that you can't
15 release if you're in spec. You just can't do it, whereas if
16 you're on the shelf life and you have to issue one of these
17 field alerts, you may actually get to keep your product out
18 there.

19 MR. HALES: Yes. I guess the response to that
20 is I can't talk to the future and the FDA nuances. Clearly,
21 in that scenario, there would be a legal assessment of this
22 as well, but I think the premise of this whole theory, Your
23 Honor, is that we're not going to comply with our
24 specification, and that's what the cases I think say you
25 can't do.

11

1 I think --

2 THE COURT: I hear you, but I mean at the end of
3 the day, right, I mean, really, you're going to bind your
4 client to say that if its product ends up on the market and
5 there's a random test to determine that, in fact, there's at
6 least one, I don't know if it comes in a bottle or what,
7 but, you know, some vial of this product sitting on the
8 shelf at 23 months and it has got a pH level that infringes,
9 you're telling me -- [REDACTED]

10 [REDACTED] I mean, you are telling me and going to bind
11 Eagle going forward that it has got to take every single
12 vial off the market at that point?

13 MR. HALES: Well, I guess the point would be,
14 Your Honor, if that were to happen, certainly, there would
15 be an investigation done because we have stability products
16 on the shelf that we test for each batch periodically over
17 time to look for those things, and they would have to figure
18 out is that a one bottle, was it damaged, is it an anomaly
19 or is it representative?

20 In a scenario where it's representative, I mean,
21 they have to get with us and figure out whether it's
22 representative or an anomaly and the like. And, by the way,
23 what the case law says is at that point, Par has a 271(a)
24 claim, right, and there's product on the market that's not
25 in compliance, so they can sue us at that point.

1 But I mean that to me is the, one of the
2 important differences about the law. The cases say you
3 can't presume noncompliance with the ANDA spec when you are
4 not yet on the market, and if there is a -- something goes
5 out of spec when it's commercial, then there's a 271(a) case
6 to be filed. That's exactly what happened in the
7 Barr/Elan -- sorry, Bayer/Elan, which we cited, and
8 Bayer/Biovail, which Par has cited.

9 If you look at the 30-milligram example in the
10 Elan case that we cited, it is a milligram dose. The
11 argument was made in the initial case that the spec was --
12 didn't allow infringement. There was a finding of
13 noninfringement affirmed by the Federal Circuit and the
14 argument was made that you should be looking to batch data
15 and the like or other data that would suggest that they
16 weren't going to be able to comply with the spec or there
17 was going to be some out-of-spec activity, and the Court
18 said no. And then in the subsequent case on the
19 30-milligram dose, there was a commercial product on the
20 market that they argued without a spec and there was a
21 271(a) claim.

22 So here I think their point is that their
23 theory, [REDACTED], which obviously is the theory
24 itself and on the merits we'll dispute at a later date, but
25 [REDACTED], there's no room for that in a situation

13

1 where there is not commercial product on the market and you
2 just have an ANDA spec where we're asking for approval of
3 something that can't infringe with compliance.

4 THE COURT: But they've brought an action under
5 271(a) through (c) and they've asked for declaratory relief.
6 I mean, why doesn't that alone cover it? If you put
7 aside -- I think you can almost put aside Waxman.

8 If you know somebody is on the verge of letting
9 a product go and you've got evidence that over the course of
10 its shelf life it's going to infringe, why can't you just
11 bring a regular old patent action at that point, and haven't
12 they really done that?

13 MR. HALES: I don't think that's a viable claim
14 and that could literally be a very short section of the end
15 of our SJ motion. It would be. There's no -- we have no
16 commercial product on the market and all of the activity
17 that we've done is exempt from infringement. Right? So
18 they can't state a 271(a) claim right now.

19 THE COURT: All right. Let me hear from the
20 plaintiff.

21 MR. BLACK: Thank you, Your Honor. Martin
22 Black.

23 I think Your Honor has accurately assessed the
24 cases. The first case that they cited, Elan, was an early
25 case, and the follow-on case is particularly Tyco

1 Healthcare, and even interestingly another case in that same
2 line with Elan says that the ANDA gives you a starting
3 point, but if there's evidence in the record to suggest that
4 the ANDA doesn't tell the whole story, then that can create
5 an issue of fact. And in the type of case in particular,
6 the Court said we found it significant in Elan, the case
7 they rely on, that the patent owner did not allege that the
8 generic manufacturer's commercial product would infringe in
9 spite of the ANDA spec. We've made that allegation and
10 we've backed it up with evidence and this is summary
11 judgment.

12 Ironically, in the second round of the Bayer
13 litigation, there was a 60-milligram ANDA which they keep
14 ignoring. There was a 60-milligram ANDA. Because by the
15 time that ANDA was challenged, there was additional evidence
16 available, the Court said, fine. We can have a different
17 view about what happens with the 60s and the 30s.

18 So we're here on summary judgment. The law says
19 you rely on the ANDA and all available evidence to predict
20 what will happen in the future, and, by the way, you do the
21 same thing with respect to a 271(a) claim, which is not
22 bound by any of the -- even if you accept their view of the
23 law in Hatch-Waxman, you are correct, it wouldn't bind on
24 271(a), which is just a straight-up base. They're ready to
25 go to market. [REDACTED]

1 [REDACTED]
2 The second was a representation about the law
3 that all you do is look at the ANDA, which Your Honor
4 observed is not the law.

5 And the third is that the result we're relying
6 on is an anomaly, and it is clearly not an anomaly based on
7 the evidence, and in any case, if that evidence is disputed,
8 can form no basis for summary judgment.

9 Thank you.

10 THE COURT: All right. Let me just ask one --

11 MR. BLACK: Your Honor.

12 THE COURT: Yes. Hold on. Mr. Black, let me
13 just ask you one question. You know, you talked about that
14 you could show that at some point during the distribution
15 chain, the product could be infringing. You know, what do
16 you have to prove to show that it could be? That does seem
17 speculative.

18 MR. BLACK: No, it's not speculative, Your
19 Honor. It's a question of what you have to prove in a
20 Hatch-Waxman case before the product is on the market.

21 We have to show that there's a reasonable
22 likelihood that they'll infringe and [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

15

1 [REDACTED]
2 [REDACTED] They want to go, and we say if
3 they do, they're going to infringe. We bring all evidence
4 to bear. We have an expert opinion and that should be
5 sufficient.

6 Now, the one thing that I want to amplify is
7 that the claims at issue in the case are method claims for
8 administering a drug with a unit dosage form with a pH
9 of 3.7, 3.8, 3.9, and just because they release the product
10 on a particular day [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

15 But, most importantly, this is summary judgment.
16 There are lots of, at a minimum, fact issues. If anything,
17 we believe we would be entitled to summary judgment, but
18 certainly, this is not a good candidate for an expedited
19 summary judgment process or to go around the rule as we
20 usually have in ANDA cases, you have no summary judgment.
21 But I will point out that we got here based on three
22 representations that were made at the last hearing, which
23 were not completely accurate.

24 The first was a procedural representation that
25 we had to do this because [REDACTED]

17

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]

5 So we know that if they sell within their spec,
6 it's [REDACTED], [REDACTED]

7 [REDACTED]
8 Now, they could remove the problem by [REDACTED]
9 [REDACTED] in which case there would be no proof available that
10 the product would ever [REDACTED], in all likelihood.

11 But they decided not to do that, and that's important here,
12 because they understood that they had a batch they made, one
13 of their three batches for the FDA process. They made it at
14 [REDACTED]. They could have dealt
15 with the problem, but they decided not to, and they're
16 continuing to try to get approval of that ANDA.

17 So as long as they reserve the right to sell at
18 [REDACTED] which they do and which we had to assume they can do
19 under the Sunovion case, they are taking -- they are selling
20 a product which we know is going to ultimately fall into our
21 range.

22 THE COURT: All right. Okay. And I mean
23 another way I guess of just kind of responding to my
24 question is essentially, right, I mean, Hatch-Waxman, it is
25 all about an injunction. That's why reasonable likelihood

1 is a standard.

2 MR. BLACK: Right.

3 THE COURT: That's why it could infringe is
4 really the operative question.

5 MR. BLACK: That's right, Your Honor.

6 THE COURT: Okay. I had to figure that out in
7 my own brain.

8 All right. Let me hear. Eagle wanted to
9 respond.

10 MR. HALES: Yes. Thanks, Your Honor. And just
11 to be clear, I mean, Mr. Black is suggesting that these
12 things are definitive and, again, these are for another day,
13 but just to note, we disagree with this theory.

14 THE COURT: I understand. I get that. You
15 don't have to repeat that. I understand that fully.

16 MR. HALES: What they've done is wholly
17 speculative. There's no data that behaves the way they are
18 suggesting. So they've got a -- they've looked at some
19 data. They've suggested that there is a [REDACTED],
20 and then they're applying it to a different set of batches.
21 Right?

22 So --

23 THE COURT: I hear you, but at the end of the
24 day, those are facts, right, I mean, that you will have your
25 experts testify and very differently about this and then I

1 resolved the question of infringement, when you don't have
2 commercial product on the market, the ANDA specification
3 controls.

4 And we are --

5 THE COURT: But how do you square that, how do
6 you square that statement with Tyco? I mean, in Tyco the
7 Court held, "It is not unreasonable for a patent owner to
8 allege infringement under Section 271(E)(2)(a) if the patent
9 owner has evidence that the as marketed commercial ANDA
10 product will infringe even though the hypothetical product
11 specified in the ANDA could not infringe," unquote?

12 You can say it rises and falls with the
13 specification. I agree there's language in Elan that says
14 that, but I think it's under very, very, you know, limited
15 facts that aren't here.

16 So tell me, how do you distinguish what I just
17 read from Tyco healthcare?

18 MR. HALES: I mean, the Tyco Healthcare is
19 actually a Noerr-Pennington case. I would take it the
20 reverse. I understand the language here. Number one, the
21 difference is we do not have any commercial product on the
22 market that suggest any contrary behavior to the
23 specification, so that's a difference. It doesn't assist
24 now.

25 And, again --

19

1 guess I will have to decide.

2 MR. HALES: I agree on the point that they're
3 trying to raise a dispute, Your Honor, but this is I think
4 why the cases say what they say in terms of the
5 specifications.

6 One of the things that Mr. Black said was that
7 [REDACTED]
8 [REDACTED], and we didn't put this in
9 the summary judgment motion because that would have probably
10 raised a bunch of fact disputes that are not germane to the
11 ANDA specification control of line of case law.

12 Our point is that the FDA has our data. They
13 have our specification, [REDACTED]
14 [REDACTED] We've given them the data and more
15 data than Mr. Black is talking about, and they also are
16 aware of [REDACTED]

17 [REDACTED]
18 [REDACTED] And the FDA's job
19 is to evaluate whether they are confident that we can meet
20 our requested specification, and if they approve it, then
21 they believe that we can, and our goal is, of course, to
22 design a product that meets it.

23 And that's why I think the line of cases that
24 are out there are so clear that when the specification
25

21

1 THE COURT: Well, now you are back to facts, but
2 I'm commenting on your statement, your opening statement
3 that this rises and falls with the specification.

4 MR. HALES: Yes. The cases that have actually
5 been -- Tyco is a Noerr-Pennington case on whether it was
6 sham litigation or not. The cases that really confront the
7 issue of are we going -- when there's no commercial product
8 on the market, are we going to look at the ANDA
9 specification or beyond it when the specification controls
10 our cases like Bayer and Brimonidine, which are directly on
11 point? So that to me I think squares it.

12 And Sunovion, the ANDA specification range
13 overlapped the claimed range, so that's a totally different
14 scenario. This is a scenario where what we're asking the
15 FDA to approve is something that has no overlap with the
16 claimed range, and if they approve it, we have demonstrated
17 to them to their satisfaction that we're going to be able to
18 make that product, and that's on us to demonstrate and it's
19 on them to review.

20 And that is why I think these cases --

21 THE COURT: Do you --

22 MR. HALES: Sorry.

23 THE COURT: No. Go ahead. Do you dispute that
24 their expert is going to say there is overlap?

25 MR. HALES: Their whole theory, all they've

1 presented, and, number one, there's no dispute there's not a
2 commercial product out there. Their expert's theory is that
3 [REDACTED]
4 if it's for a product that is released at [REDACTED] into the
5 patented range, the claimed range. That necessarily
6 presumes noncompliance with our specification. That's their
7 main point.

8 THE COURT: But just to be clear, I just want to
9 make sure. I mean, you do admit, right, their expert is
10 saying something that overlapped? In other words, there is
11 overlap according to their expert? You just don't believe
12 their expert?

13 MR. HALES: No, no, no. Their expert is making
14 the statement that [REDACTED] into the
15 claimed range. That is true.

16 THE COURT: Okay.

17 MR. HALES: We disagree with that, but that's
18 what they are saying. My point is that his theory,
19 accepting his theory presumes and requires presuming that we
20 will not comply with our ANDA specification, and that's what
21 the law says the District Court and the parties should not
22 be presuming.

23 THE COURT: But the only thing you are presuming
24 is the stability specifications will not be complied with.
25 Correct?

23

1 MR. HALES: Well, we have to comply with all of
2 them. Your point --

3 THE COURT: I know that. I just want to make
4 sure I understand. Their expert, the presumption that you
5 are identifying that their expert makes is a presumption
6 that you will not comply with the [REDACTED] requirements.
7 Is that correct?

8 MR. HALES: Correct. I think he is accepting
9 that we will comply with our [REDACTED] requirements.

10 THE COURT: Right. I just want to make sure.

11 MR. HALES: And what's interesting and the point
12 I wanted to make and I didn't before, Your Honor, but their
13 letter is completely silent on the [REDACTED] requirement.
14 But that's part of our ANDA, is the [REDACTED] --

15 THE COURT: No, no. Actually, I don't think
16 they are. I mean, maybe I teased it out more than they
17 expressed, but I understood them to be -- that is why they
18 cited these field alerts.

19 Maybe, Mr. Black, do you want to speak to that?

20 MR. BLACK: You're absolutely right, Your Honor.
21 Put the Hatch-Waxman stuff aside for a moment. Just imagine
22 that we're a regular old patent case. They're threatening
23 a launch of products which they say they're going to sell
24 at [REDACTED] Our expert comes in. He says, hey [REDACTED]
[REDACTED]

1 [REDACTED]
2 We win at that point. They can't come in and
3 say, oh, the FDA thinks we're going to be okay based on
4 data we provided during the ANDA and we've got an expert
5 who says that data, the FDA didn't even review it
6 completely. They didn't review an infringement question,
7 and our expert says, [REDACTED] We would have to
8 have a trial over that.

9 Maybe the FDA's implicit view is somehow the
10 evidence, or actually I doubt it. But we have a dispute of
11 the experts here at best about whether the product is sold
12 at [REDACTED] [REDACTED]

13 [REDACTED] There's no way they can get summary
14 judgment.

15 And the continued misrepresentation that the
16 case law binds in some fashion, it flies in the face of the
17 wording of Tyco and it's just inconsistent. We have to deal
18 with reality in Hatch-Waxman just like anything else. We
19 have an expert report that says [REDACTED]
20 and that's sufficient to get over the limited bar for
21 summary judgment.

22 THE COURT: Okay. So I'm going to deny the
23 application to file for summary judgment. I think although
24 there's language in the Elan decision, I think the
25 subsequent cases make clear, and I think, frankly, I think

25

1 the language of Tyco Healthcare requires that I deny summary
2 judgment and that this turns and falls solely on the
3 language in the specification.

4 And I think as far as the anomaly argument, I
5 mean, that's a classic factual dispute that we'll hear from
6 the experts at trial and I will make a decision.

7 All right. So that application is denied. So
8 now we're on -- what's next? Let's hear from plaintiffs.

9 MR. BLACK: Thank you, Your Honor. So we have
10 a 30-month stay that expires in October. We have no
11 tentative --

12 THE COURT: Wait. Hold on. I guess I failed to
13 appreciate that. The stay that's involved in this case is
14 going to expire in October coming up?

15 MR. BLACK: That's correct, Your Honor.

16 THE COURT: Okay.

17 MR. BLACK: They do not have -- and on the last
18 call, which was a call primarily for the scheduling problem
19 that we couldn't have a trial on May 18th, they offered the
20 solution of having a summary judgment process, so we had an
21 impromptu summary judgment argument where we were -- you
22 know, did what we could. Now we've gone through that
23 process, the application is denied.

24 And they also represented that they were --

25 THE COURT: Mr. Black, Mr. Black, just so you

1 know, you got cut off.

2 MR. BLACK: Oh. I'm sorry, Your Honor.

3 THE COURT: I'm not sure it was really worth
4 making the point. If you want to rehash that they made a
5 summary judgment application, they did, and --

6 MR. BLACK: No, no, no. I was just saying how
7 we got here. We had a conference to talk about the
8 schedule.

9 THE COURT: Right. All right. So what about
10 next steps? We don't have much time.

11 MR. BLACK: Right. So I think they don't have
12 tentative approval. [REDACTED].

13 [REDACTED]
14 [REDACTED] That could be a thumbs up,
15 thumbs down, or anything in between, and so we don't know
16 where we are, but we don't have an approved product yet. So
17 my suggestion would be that we reconvene [REDACTED]
18 [REDACTED], and we do have a trial set
19 in the companion cases for January.

20 Now, we could roll this case into that one and
21 do them all together. If they get tentative approval, we
22 can negotiate an extension to the stay, or if we have to, we
23 can come back to Your Honor and ask for relief, but I'm not
24 sure what else we can do at this point.

25 THE COURT: All right. Let me hear from the

1 trial so that we don't lose, if at all possible, all of the
2 blood, sweat and investment that the client put in to having
3 this, having this time advantage against the other generics
4 that are waiting to come on some time after a January trial
5 date.

6 THE COURT: Okay. When can you go to trial?

7 MR. HALES: Well, we're --

8 THE COURT: Let's assume for right now that
9 we're doing in-person trials starting June 15th. When can
10 you go to trial?

11 MR. HALES: Well, as soon as June 15th after
12 we're available, I think we'll be ready. I have not talked
13 to an expert or anybody in particular. We will move heaven
14 and earth to go when the Court could give us, when Your
15 Honor could give us a trial date.

16 MR. BLACK: Your Honor, we have not talked to
17 our experts to figure out who can travel. We've got doctors
18 and other things in the case.

19 We had originally, I think when we were on the
20 phone the last time, Your Honor said that the trial would be
21 not before September or October, which is why we had
22 suggested combining this with the next case. They get there
23 180 days of exclusivity as the first filer.

24 THE COURT: So help me understand that, because
25 I mean I don't see how it would really work to do a trial

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1 defense.

2 MR. HALES: Yes, Your Honor. Bryan Hales.
3 Thank you.

4 So the FDA, we believe it's Covid related. [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]

8 But just to reiterate our points from the last
9 call, the October trial date that we had before the Covid
10 situation was very important to our client because [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]

14 And so I know obviously things got taken away
15 from us through no fault of anybody in terms of the virus
16 situation, but we are very interested in getting to a trial
17 in some fashion, and I don't know what the Court is thinking
18 in terms of Zoom or live trials from a timing standpoint,
19 but it is not -- we're definitely not -- we would hope very
20 much not to be waiting for a January trial and have some way
21 to have a trial ahead of that.

22 The parties have our pretrial submissions done,
23 and on the last call Your Honor asked us to proceed with
24 those, which we were in favor of, and so those are ready.
25 We just need to understand what options we have to have a

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1 between now and September, which is why I said it. I've
2 got to admit, I think when I said it, I may not have
3 realized there was an October end date for the stay.
4 Maybe I did.

5 MR. BLACK: Yes. We had discussed it, Your
6 Honor. The client pointed out they didn't have tentative
7 approval, so perhaps it wasn't as urgent as it sounded and
8 Your Honor wondered why we would have a trial without
9 tentative approval. [REDACTED]
10 [REDACTED] And so I think
11 we're still in a position where they don't have an approved
12 product. [REDACTED]
13 [REDACTED]
14 [REDACTED]

15 THE COURT: So let's just spell this out. I
16 mean, I want to do justice to both sides, but, you know, I
17 also -- your summary of my reaction I'm sure is accurate to
18 the extent it was why am I having a trial on an unapproved
19 product. That's for sure.

20 MR. BLACK: The -- sorry.

21 THE COURT: No. I'm just trying to figure out,
22 you know, trying to be fair to both sides, what works here.
23 I mean, I've got two cases that are going to trial in
24 September and they are retrials. Rather, one is a retrial.
25 It is definitely going to trial. The following week it's a

1 very significant pharmaceutical case and it's going to
2 trial. Those are jury cases. And then I've got six
3 Markmans in September, and so I just don't see how we're
4 going to go to trial in September in this case.
5 You know, you mentioned they've got the
6 180 days. They lose that, though, right, if we go to trial
7 in January. No?
8 MR. BLACK: No, no. They get -- they keep their
9 180 days. It doesn't matter when we go to trial. They have
10 priority over anybody else on the same dosage strength. We
11 filed a similar application.
12 THE COURT: Okay.
13 MR. HALES: Your Honor, this is Bryan Hales. If
14 I can respond to that?
15 THE COURT: Yes, please.
16 MR. HALES: He's being very careful about the
17 way he words that. One of the defendants in that other
18 case, American Regent, we do not have exclusivity against,
19 so the advantage that we have against them, the competitive
20 advantage is the one that we invested in to have a time
21 advantage based on being ahead of them, but if we are with
22 them at trial, they are coming on at the same time that we
23 come on. There's no 180-day exclusivity for them.
24 MR. BLACK: They're actually -- well, we just
25 settled with them and they have approval, so there's no --

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1 we may need to flesh this out in a letter or something, Your
2 Honor. It's a little complicated, but there's no -- there's
3 no prejudice to them. They get a 180-day jump on the other
4 defendants if they prevail because they are the first filer.
5 There's this --
6 THE COURT: Well, wait. You are saying they are
7 going to get a 180-day jump on the party that you just
8 settled with that Mr. Hales pointed out as the same --
9 MR. BLACK: No, I'm not saying that. I must be
10 careful not to disclose any terms of the settlement on the
11 call.
12 THE COURT: Okay.
13 MR. BLACK: But it's not -- it's not a -- I need
14 to back up a step, Your Honor, if you will.
15 So they filed on one dosage strength, Eagle
16 did, and there's another dosage strength that Sandoz filed
17 on.
18 On the dosage strength that Eagle filed on when
19 they would have the right to the 180 days, all of the other
20 defendants are behind them stacked up except Eagle filed a
21 different kind of -- excuse me. American Regent filed a
22 different type of filing, so they were never behind Eagle
23 and never will be behind Eagle. So the investment that he's
24 talking about, I don't know what that means. They use
25 different regulatory paths.

1 That case is now settled though, and I don't
2 want to disclose the terms on the call here, but the
3 argument that they won't get their -- they won't get what
4 they would be entitled to, 180 days, is not correct.
5 THE COURT: Okay. Well, I mean, I'm just trying
6 to get some kind of comfort level about what the right
7 answer is here because it affects trying to set a trial
8 date.
9 MR. BLACK: So --
10 THE COURT: Now, I've heard from other judges,
11 which is just, you know what, the parties can do what the
12 parties want. I mean, we can only do so much here
13 schedulingwise, and so, you know, I guess to that extent,
14 the burden is really on Eagle to explain what it wants
15 and why we can't just do this in January, and you should
16 somehow -- I mean, is there no recourse to compensate for
17 this first filing privilege you have?
18 MR. HALES: Well, I don't understand what the
19 parameters are of the settlement that Mr. Black is talking
20 about because I've just heard of it, so I can't comment on
21 it. Certainly, we did invest in getting our ANDA filed and
22 the trial date that we had before Coronavirus to get ahead
23 of the other players however they filed, and that's what
24 we've been trying to protect.
25 We want to make sure that we're ahead of -- even

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1 as to a, like, a Sandoz with a different dose, you know, we
2 still had a competitive posture that was favorable to us
3 because we were just earlier than them, whatever dose that
4 they come on with, because different doses come out of the
5 generics and people will take them up.
6 So we're trying to protect that even with
7 American Regent gone. Again, I would have to see that
8 agreement to understand nuances and the appropriate parts of
9 it, but that's still important to us and I think it still
10 has value. We can provide more on that maybe after we've
11 had a chance to understand what it is that Mr. Black is
12 trying to convey.
13 As to the approval point, I just want to make
14 one point clear on the tentative approval issue. Trials
15 happen, and they happen in Delaware sometimes after
16 tentative approval was had and sometimes before. That's
17 kind of the ANDA framework. Right? The case gets filed
18 when we filed the ANDA. And the ANDAs proceed towards --
19 you know, the generic filer needs to have two things to
20 get on the market. They need to have approval and they need
21 to have cleared the Paragraph 4 litigation pathway. And
22 both of those things have to happen preferably, or you want
23 them to happen before the stay, if you can.

24 [REDACTED]
25 [REDACTED]

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 I don't know -- Your Honor, I don't know if the
5 Court is contemplating Zoom trials or anything like that
6 that would allow us to advance, especially in a non-jury
7 scenario. Right? Advance --
8 THE COURT: Well, I'm definitely not
9 contemplating Zoom because my understanding from the folks
10 in the judicial branch is it's not working that great. We
11 have used the Cisco system, but it's difficult. I had one
12 hearing. Granted, it was a criminal matter and it involved
13 a translator, so it exacerbated the difficulties, but it's
14 just not a very good -- it is very I don't think conducive
15 to, you know, making credibility determinations in a way you
16 normally would with a live witness.
17 MR. BLACK: Your Honor, here's the issue. If
18 they don't get a tentative approval [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]
25 [REDACTED]

1 But the bottom line is, as a practical matter,
2 they don't have an approved product and we ought to wait and
3 see if they get one. If they get one [REDACTED]
4 he's right. We put the pretrial order in. We can figure
5 out when to have a trial. We can be creative, but if they
6 don't, then it seems like we are trying to move heaven and
7 earth for no reason.
8 MR. HALES: Your Honor, if I can just add, I
9 think Mr. Black has gotten quite a bit ahead of this on his
10 suggestion as to why we do or don't -- why we don't have
11 approval yet, but just from a timing perspective, I would
12 agree that [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 But the one concern we have is we don't have the
21 same exact patent as the case in January, so there's not
22 going to be a different -- a total overlap. We're just
23 trying, our client -- and, again, I'm not the FDA either,
24 [REDACTED]
25 [REDACTED]

35

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]. Unlike Mr. Hales, willing to say over
6 and over again that they have been saying to us for 18
7 months, we're getting approval tomorrow as they try and
8 negotiate and tell various judges, you know, what's going to
9 happen. [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 And so then we'd be doing a trial in October on
13 the same patent for Eagle coming back for another trial in
14 January on the same patent, enormous expense, eating into
15 Court time.
16 And the reason we set the trial date for
17 May 18th was also because of both the 30-month stay, and we
18 wanted to give the Court enough time to make a decision, but
19 also we expected they would have approval by now, and they
20 don't [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]
25 [REDACTED]

37

1 [REDACTED]
2 [REDACTED]
3 And if we -- if we get that and then haven't
4 got a trial in place at a reasonable time, then even if we
5 get it around that time, then we're going to be in front
6 of the Court potentially on some type of expedited relief.
7 Like if we have a [REDACTED]
8 [REDACTED] but we have no trial
9 scheduled because ours -- we don't have a trial scheduled,
10 then we are going to be in a TRO/PI situation. I mean,
11 these things are potentially going to come to a head around
12 that time anyway.
13 So we're just -- and, again, we're in an unusual
14 circumstance with the ability to do trials, but with a bench
15 trial, our hope is that we can put something down as a place
16 to try the case and then it's in there, [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 then we can address that situation and it's easier to remove
21 a date than put one in, I think.
22 THE COURT: Yes. Actually, this is a fair
23 assumption under normal times, but we're not in normal
24 times. And, you know, here's what my inclination is. I'm
25 not going to be adding a lot of trials, if any, to my

1 calendar between now and January, and as the normal course
2 goes, and I am hopeful that this normal course will continue
3 is cases settle, so my calendar should free up. And so what
4 I think the better course right now to do is, let's wait.

5 Let's see what happens [REDACTED]

6 Is it [REDACTED] Is that the right date, I
7 believe? Right?

8 MR. BLACK: Yes, Your Honor.

9 MR. HALES: [REDACTED]

10 THE COURT: The [REDACTED] [REDACTED]

11 [REDACTED]
12 The one thing I would say to both sides is, be
13 prepared to go. So, you know, that's what I would say. You
14 should be prepared to try this case September, October,
15 November next year -- of this year rather, and we'll try to
16 squeeze it in if we can. But I'm also not promising, and
17 we're basically at the mercy of our schedule, which is very,
18 very burdensome, and then the pandemic as well. But I
19 really don't want to try a virtual hearing. I want to do it
20 in person if I at all can. All right?

21 MR. BLACK: Yes.

22 THE COURT: So you are doing June -- and say I
23 say that because, Mr. Black, you won this little battle, but
24 you need to be prepared just to move really quickly. I
25 assume anyway you would be the one that has to move to stop

1 we can move forward. Okay?

2 So I'm not going to set up a telephone
3 conference, but the parties are both directed to inform me
4 as soon as you hear from the FDA.

5 MR. BLACK: Thank you, Your Honor.

6 MR. HALES: Understood, Your Honor. Thank you.

7 THE COURT: Okay. Anything else I need to
8 address from the plaintiffs?

9 MR. BLACK: No, Your Honor. Nothing from the
10 plaintiffs.

11 THE COURT: Anything from the defense?

12 MR. HALES: No, Your Honor. Thank you.

13 THE COURT: All right. Thank you, all, and stay
14 safe. We're done. Thanks.

15 (Telephone conference concluded at 1:53 p.m.)

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1 them from going forward in a launch, so you would be
2 prepared -- you would have to prepare yourself for a PI
3 anyway. Correct?

4 MR. BLACK: Yes, Your Honor. We can do that on
5 papers obviously, and if some testimony is necessary, it's
6 easier to deal with. What we're trying to avoid is if their
7 product is not approved, they've been telling us they're
8 going to get approval forever and they don't have it, and
9 we're going to have a trial. We're talking about two trials
10 on the same patent in October and January. All of their
11 patents are caught up to the January trial.

12 Obviously, we can do that if it's necessary.
13 We'll be ready to go. We've got the pretrial order done.
14 All of that work is done.

15 THE COURT: Okay.

16 MR. BLACK: But you're right. If they get
17 approval --

18 THE COURT: Yes. [REDACTED]

19 [REDACTED] And I
20 would just say then, the parties need to immediately notify
21 me when they have heard something from the FDA, and then
22 we'll --

23 MR. BLACK: Thank you, Your Honor.

24 THE COURT: Yes. That's how we'll just leave
25 it, and hopefully, we're going to hear something by then and

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10th [2] - 27:5, 29:10 15th [2] - 28:9, 28:11 18 [2] - 1:13, 35:6 18-823-CFC [1] - 1:10 180 [5] - 28:23, 30:6, 30:9, 31:19, 32:4 180-day [3] - 30:23, 31:3, 31:7 18th [2] - 25:19, 35:17 1:00 [2] - 1:13, 3:4 1:53 [1] - 40:15	7 [1] - 9:5 A ability [1] - 37:14 able [3] - 12:16, 21:17, 36:18 absolutely [1] - 23:20 accept [1] - 14:22 accepting [3] - 10:6, 22:19, 23:8 according [2] - 15:13, 22:11 accurate [2] - 15:23, 29:17 accurately [1] - 13:23 action [4] - 4:19, 6:1, 13:4, 13:11 ACTION [1] - 1:4 active [1] - 9:19 actively [1] - 9:17 activity [2] - 12:17, 13:16 add [1] - 36:8 adding [1] - 37:25 additional [1] - 14:15 address [2] - 37:20, 40:8 administering [1] - 15:8 admit [2] - 22:9, 29:2 advance [2] - 34:6, 34:7 advantage [5] - 27:12, 28:3, 30:19, 30:20, 30:21 affects [1] - 32:7 affirmed [1] - 12:13 afternoon [3] - 3:6, 3:8, 3:14 agree [3] - 19:2, 20:13, 36:12 agreed [1] - 9:2 agreement [1] - 33:8 ahead [9] - 5:4, 21:23, 27:12, 27:21, 30:21, 32:22, 32:25, 36:9, 36:16 alerts [2] - 10:17, 23:18 allegation [1] - 14:9 allege [3] - 6:7, 14:7, 20:8 allow [2] - 12:12, 34:6 allowable [1] - 24:12 almost [1] - 13:7 alone [1] - 13:6 American [3] - 30:18,	31:21, 33:7 amplify [1] - 15:6 analogous [1] - 8:25 AND [1] - 1:2 ANDA [30] - 3:23, 6:13, 6:25, 7:2, 9:1, 9:5, 12:3, 13:2, 14:2, 14:4, 14:9, 14:13, 14:14, 14:15, 14:19, 15:20, 16:3, 17:16, 19:11, 20:2, 20:9, 20:11, 21:8, 21:12, 22:20, 23:14, 24:4, 32:21, 33:17, 33:18 ANDAs [1] - 33:18 ANDERSON [1] - 2:12 Anderson [2] - 3:15, 3:16 anomaly [6] - 11:18, 11:22, 16:6, 17:4, 25:4 answer [3] - 4:3, 4:8, 32:7 anyway [3] - 37:12, 38:25, 39:3 APPEARANCES [2] - 1:18, 2:1 application [5] - 24:23, 25:7, 25:23, 26:5, 30:11 applying [1] - 18:20 appreciate [1] - 25:13 appropriate [1] - 33:8 approval [43] - 4:5, 4:8, 5:12, 8:5, 8:6, 8:9, 10:9, 13:2, 15:1, 15:2, 16:1, 17:16, 26:12, 26:21, 29:7, 29:9, 29:13, 30:25, 33:13, 33:14, 33:16, 33:20, 33:25, 34:18, 34:21, 34:25, 35:3, 35:7, 35:10, 35:11, 35:19, 36:11, 36:13, 36:14, 37:2, 37:8, 37:17, 37:18, 39:8, 39:17 approve [3] - 19:21, 21:15, 21:16 approved [6] - 5:21, 5:24, 26:16, 29:11, 36:2, 39:7 argued [1] - 12:20 argument [6] - 9:23, 12:11, 12:14, 25:4, 25:21, 32:3 aside [3] - 13:7, 23:21 assertion [1] - 8:18 assessed [1] - 13:23 assessment [1] -	10:21 assist [1] - 20:23 assume [3] - 17:18, 28:8, 38:25 assumption [1] - 37:23 authorization [1] - 5:11 available [5] - 14:16, 14:19, 17:9, 23:25, 28:12 avoid [1] - 39:6 aware [1] - 19:16 B backed [1] - 14:10 ball [1] - 34:1 bar [1] - 24:20 Barr/Elan [1] - 12:7 base [1] - 14:24 based [5] - 15:21, 16:6, 23:25, 24:3, 30:21 basis [2] - 15:14, 16:8 batch [5] - 11:16, 12:14, 16:22, 17:12, 19:18 batches [3] - 17:6, 17:13, 18:20 battle [1] - 38:23 Bayer [2] - 14:12, 21:10 Bayer/Biovail [1] - 12:8 Bayer/Elan [1] - 12:7 bear [1] - 15:4 BEFORE [1] - 1:16 begin [2] - 9:5, 9:25 beginning [1] - 3:4 behalf [2] - 3:9, 3:15 behaves [1] - 18:17 behavior [1] - 20:22 behind [3] - 31:20, 31:22, 31:23 believes [1] - 33:24 below [1] - 9:4 bench [1] - 37:14 best [1] - 24:11 better [1] - 38:4 between [4] - 6:18, 26:15, 29:1, 38:1 beyond [1] - 21:9 bind [3] - 11:3, 11:10, 14:23 binds [1] - 24:16 BINDU [1] - 2:12 Bindu [1] - 3:15 bit [1] - 36:9 BLACK [29] - 2:7,	13:21, 16:11, 16:18, 18:2, 18:5, 23:20, 25:9, 25:15, 25:17, 26:2, 26:6, 26:11, 28:16, 29:5, 29:20, 30:8, 30:24, 31:9, 31:13, 32:9, 34:17, 38:8, 38:21, 39:4, 39:16, 39:23, 40:5, 40:9 black [11] - 16:12, 18:11, 19:6, 19:15, 23:19, 25:25, 32:19, 33:11, 36:9, 38:23 Black [2] - 3:10, 13:22 blood [1] - 28:2 bottle [2] - 11:6, 11:18 bottom [1] - 36:1 bound [1] - 14:22 brain [1] - 18:7 branch [1] - 34:10 BRIAN [2] - 1:20, 2:7 Brian [2] - 3:8, 3:10 Brimonidine [4] - 8:24, 9:23, 21:10 bring [2] - 13:11, 15:3 brought [1] - 13:4 Brown [1] - 3:11 BRYAN [1] - 2:17 Bryan [4] - 3:17, 4:1, 27:2, 30:13 bunch [1] - 19:10 burden [1] - 32:14 burdensome [1] - 38:18 business [1] - 34:19 BY [5] - 1:20, 2:3, 2:7, 2:12, 2:17 C calendar [2] - 38:1, 38:3 candidate [1] - 15:18 cannot [1] - 9:8 careful [2] - 30:16, 31:10 case [37] - 6:21, 8:24, 9:2, 11:23, 12:5, 12:10, 12:11, 12:18, 13:24, 13:25, 14:1, 14:5, 14:6, 15:7, 16:7, 16:20, 17:9, 17:19, 19:11, 20:19, 21:5, 23:22, 24:16, 25:13, 26:20, 28:18, 28:22, 30:1, 30:4, 30:18, 32:1, 33:17, 36:21, 37:16, 37:19, 38:14
2 2020 [1] - 1:13 23 [1] - 11:8 24 [1] - 19:17 24-month [1] - 19:18 271(a) [7] - 11:23, 12:5, 12:21, 13:5, 13:18, 14:21, 14:24 271(E)(2)(a) [1] - 20:8 28th [3] - 38:9, 38:10, 39:18 29th [3] - 38:5, 38:6, 39:19				
3 3 [1] - 17:9 3.64 [8] - 15:10, 16:24, 17:6, 17:14, 17:18, 22:4, 23:24, 24:12 3.7 [6] - 15:9, 15:12, 15:13, 23:25, 24:7, 24:19 3.8 [1] - 15:9 3.9 [1] - 15:9 30-milligram [2] - 12:9, 12:19 30-month [4] - 25:10, 33:25, 35:17, 36:16 30s [1] - 14:17				
4 4 [1] - 33:21				
6 6.5 [2] - 9:1, 9:4 6.7 [1] - 9:1 60-milligram [2] - 14:13, 14:14 60s [1] - 14:17				

<p>cases [22] - 6:12, 6:18, 6:20, 6:22, 7:4, 8:16, 8:23, 10:24, 12:2, 13:24, 15:20, 19:4, 19:24, 21:4, 21:6, 21:10, 21:20, 24:25, 26:19, 29:23, 30:2, 38:3</p> <p>caught [1] - 39:11</p> <p>certainly [3] - 11:14, 15:18, 32:21</p> <p>chain [2] - 15:11, 16:15</p> <p>challenged [1] - 14:15</p> <p>chance [3] - 33:11, 34:20, 34:21</p> <p>change [2] - 5:14, 7:10</p> <p>characteristic [2] - 17:1, 17:3</p> <p>Circuit [6] - 6:12, 6:23, 9:8, 10:1, 10:3, 12:13</p> <p>circumstance [1] - 37:14</p> <p>circumstances [1] - 29:14</p> <p>Cisco [1] - 34:11</p> <p>cited [5] - 12:7, 12:8, 12:10, 13:24, 23:18</p> <p>CIVIL [1] - 1:4</p> <p>claim [5] - 11:24, 12:21, 13:13, 13:18, 14:21</p> <p>claimed [4] - 21:13, 21:16, 22:5, 22:15</p> <p>claims [4] - 8:25, 9:6, 15:7</p> <p>classic [1] - 25:5</p> <p>clear [7] - 15:12, 18:11, 19:25, 22:8, 24:25, 33:14, 35:9</p> <p>cleared [1] - 33:21</p> <p>clearly [5] - 6:2, 6:23, 8:19, 10:20, 16:6</p> <p>client [9] - 9:17, 11:4, 27:10, 28:2, 29:6, 33:24, 36:23, 36:24</p> <p>colleague [1] - 3:16</p> <p>COLM [1] - 1:16</p> <p>combining [1] - 28:22</p> <p>comfort [3] - 7:1, 7:12, 32:6</p> <p>coming [3] - 25:14, 30:22, 35:13</p> <p>comment [3] - 32:20, 34:22, 34:23</p> <p>commenting [1] - 21:2</p> <p>commercial [11] - 6:14, 12:5, 12:19,</p>	<p>13:1, 13:16, 14:8, 20:2, 20:9, 20:21, 21:7, 22:2</p> <p>companion [1] - 26:19</p> <p>COMPANY [1] - 1:6</p> <p>compensate [1] - 32:16</p> <p>competitive [3] - 27:11, 30:19, 33:2</p> <p>completely [3] - 15:23, 23:13, 24:6</p> <p>compliance [5] - 4:4, 6:24, 9:18, 11:25, 13:3</p> <p>complicated [1] - 31:2</p> <p>complied [2] - 7:3, 22:24</p> <p>comply [8] - 6:12, 10:23, 11:9, 12:16, 22:20, 23:1, 23:6, 23:9</p> <p>comport [1] - 7:18</p> <p>concern [1] - 36:20</p> <p>concerned [1] - 5:18</p> <p>concluded [1] - 40:15</p> <p>conductive [1] - 34:14</p> <p>conference [5] - 1:14, 3:3, 26:7, 40:3, 40:15</p> <p>confident [1] - 19:20</p> <p>confront [1] - 21:6</p> <p>confused [1] - 4:12</p> <p>CONNOLLY [1] - 1:16</p> <p>considerations [1] - 7:25</p> <p>considered [1] - 6:9</p> <p>contemplating [3] - 4:19, 34:5, 34:9</p> <p>context [2] - 8:20, 8:21</p> <p>continue [2] - 4:15, 38:2</p> <p>Continued [1] - 2:1</p> <p>continued [2] - 8:1, 24:15</p> <p>continuing [1] - 17:16</p> <p>contrary [2] - 10:8, 20:22</p> <p>control [1] - 19:11</p> <p>controls [2] - 20:3, 21:9</p> <p>convey [1] - 33:12</p> <p>Coronavirus [1] - 32:22</p> <p>correct [7] - 14:23, 22:25, 23:7, 23:8, 25:15, 32:4, 39:3</p> <p>CORROON [1] - 2:12</p> <p>Counsel [2] - 2:9, 2:19</p> <p>course [5] - 13:9,</p>	<p>19:22, 38:1, 38:2, 38:4</p> <p>COURT [59] - 1:1, 3:6, 3:12, 3:19, 4:10, 4:23, 4:25, 6:17, 8:11, 9:12, 10:13, 11:2, 13:4, 13:19, 16:10, 16:12, 17:22, 18:3, 18:6, 18:14, 18:23, 20:5, 21:1, 21:21, 21:23, 22:8, 22:16, 22:23, 23:3, 23:10, 23:15, 24:22, 25:12, 25:16, 25:25, 26:3, 26:9, 26:25, 28:6, 28:8, 28:24, 29:15, 29:21, 30:12, 30:15, 31:6, 31:12, 32:5, 32:10, 34:8, 37:22, 38:10, 38:22, 39:15, 39:18, 39:24, 40:7, 40:11, 40:13</p> <p>Court [14] - 1:24, 10:2, 12:17, 14:6, 14:16, 20:7, 22:21, 27:17, 28:14, 34:1, 34:5, 35:15, 35:18, 37:6</p> <p>cover [1] - 13:6</p> <p>covered [1] - 3:25</p> <p>Covid [2] - 27:4, 27:9</p> <p>create [1] - 14:4</p> <p>creative [1] - 36:5</p> <p>credibility [1] - 34:15</p> <p>criminal [1] - 34:12</p> <p>cut [1] - 26:1</p>	<p>17:15</p> <p>decision [3] - 24:24, 25:6, 35:18</p> <p>declaratory [1] - 13:5</p> <p>defendant [1] - 3:15</p> <p>Defendant [2] - 1:10, 2:19</p> <p>defendants [4] - 27:13, 30:17, 31:4, 31:20</p> <p>defense [2] - 27:1, 40:11</p> <p>definitely [3] - 27:19, 29:25, 34:8</p> <p>definitive [1] - 18:12</p> <p>DELAWARE [1] - 1:2</p> <p>Delaware [2] - 1:12, 33:15</p> <p>demonstrate [1] - 21:18</p> <p>demonstrated [1] - 21:16</p> <p>denied [2] - 25:7, 25:23</p> <p>deny [2] - 24:22, 25:1</p> <p>design [1] - 19:23</p> <p>determination [1] - 7:21</p> <p>determinations [1] - 34:15</p> <p>determine [2] - 7:25, 11:5</p> <p>difference [6] - 6:17, 7:3, 8:4, 10:13, 20:21, 20:23</p> <p>differences [1] - 12:2</p> <p>different [15] - 4:24, 5:21, 6:7, 7:5, 9:13, 14:16, 18:20, 21:13, 31:21, 31:22, 31:25, 33:1, 33:4, 36:22</p> <p>differently [1] - 18:25</p> <p>difficult [2] - 34:11, 36:19</p> <p>difficulties [1] - 34:13</p> <p>directed [1] - 40:3</p> <p>directly [1] - 21:10</p> <p>disagree [3] - 8:17, 18:13, 22:17</p> <p>disclose [2] - 31:10, 32:2</p> <p>discussed [1] - 29:5</p> <p>dispute [7] - 7:8, 12:24, 19:3, 21:23, 22:1, 24:10, 25:5</p> <p>disputed [1] - 16:7</p> <p>disputes [1] - 19:10</p> <p>distinguish [1] - 20:16</p> <p>distribution [2] - 15:11, 16:14</p>	<p>DISTRICT [2] - 1:1, 1:2</p> <p>District [2] - 10:2, 22:21</p> <p>do-able [1] - 36:18</p> <p>doctors [1] - 28:17</p> <p>dollars [1] - 27:11</p> <p>done [10] - 11:15, 13:12, 13:17, 18:16, 27:22, 36:14, 36:16, 39:13, 39:14, 40:14</p> <p>door [1] - 8:8</p> <p>dosage [5] - 15:8, 30:10, 31:15, 31:16, 31:18</p> <p>dose [4] - 12:10, 12:19, 33:1, 33:3</p> <p>doses [1] - 33:4</p> <p>doubt [1] - 24:10</p> <p>down [4] - 9:2, 16:25, 26:15, 37:15</p> <p>drift [9] - 8:18, 9:2, 10:7, 12:23, 12:25, 22:3, 22:14</p> <p>drug [1] - 15:8</p> <p>due [1] - 27:7</p> <p>during [6] - 3:24, 4:7, 9:4, 16:14, 23:25, 24:4</p>
E				
<p>Eagle [15] - 3:13, 3:16, 3:22, 6:11, 8:5, 11:11, 18:8, 31:15, 31:18, 31:20, 31:22, 31:23, 32:14, 35:13</p> <p>EAGLE [1] - 1:9</p> <p>early [2] - 13:24, 35:21</p> <p>earth [2] - 28:14, 36:7</p> <p>easier [2] - 37:20, 39:6</p> <p>eating [1] - 35:14</p> <p>either [1] - 36:23</p> <p>Elan [8] - 6:21, 7:1, 12:10, 13:24, 14:2, 14:6, 20:13, 24:24</p> <p>ELLIS [1] - 2:16</p> <p>Ellis [1] - 3:18</p> <p>end [12] - 11:2, 13:14, 16:24, 17:6, 17:7, 18:23, 26:14, 26:18, 29:3, 34:18, 34:25, 36:3</p> <p>ENDO [1] - 1:5</p> <p>ends [1] - 11:4</p> <p>enormous [1] - 35:14</p> <p>ensure [1] - 9:18</p> <p>entitled [2] - 15:17, 32:4</p> <p>especially [1] - 34:6</p> <p>ESQ [8] - 1:20, 2:3,</p>				

<p>2:7, 2:7, 2:12, 2:13, 2:17, 2:17</p> <p>essentially [2] - 6:22, 17:24</p> <p>evaluate [1] - 19:20</p> <p>evidence [12] - 5:14, 13:9, 14:3, 14:10, 14:15, 14:19, 15:3, 15:12, 16:7, 20:9, 24:10</p> <p>exacerbated [1] - 34:13</p> <p>exact [1] - 36:21</p> <p>exactly [1] - 12:6</p> <p>example [1] - 12:9</p> <p>except [1] - 31:20</p> <p>exception [3] - 4:15, 5:5, 5:13</p> <p>exclusivity [3] - 28:23, 30:18, 30:23</p> <p>excuse [1] - 31:21</p> <p>exempt [1] - 13:17</p> <p>expected [2] - 5:21, 35:19</p> <p>expecting [1] - 27:5</p> <p>expedited [2] - 15:18, 37:6</p> <p>expense [1] - 35:14</p> <p>expert [15] - 4:18, 8:3, 15:4, 21:24, 22:9, 22:11, 22:12, 22:13, 23:4, 23:5, 23:24, 24:4, 24:7, 24:19, 28:13</p> <p>expert's [1] - 22:2</p> <p>experts [4] - 18:25, 24:11, 25:6, 28:17</p> <p>expire [1] - 25:14</p> <p>expires [1] - 25:10</p> <p>explain [1] - 32:14</p> <p>expressed [1] - 23:17</p> <p>extension [1] - 26:22</p> <p>extent [2] - 29:18, 32:13</p> <p>extrinsic [1] - 6:25</p>	<p>29:22, 37:22</p> <p>fairly [1] - 6:19</p> <p>fall [2] - 3:24, 17:20</p> <p>falls [3] - 20:12, 21:3, 25:2</p> <p>far [2] - 3:21, 25:4</p> <p>FARNAN [3] - 1:19, 1:20, 3:8</p> <p>Farnan [1] - 3:9</p> <p>fashion [2] - 24:16, 27:17</p> <p>fast [1] - 34:3</p> <p>fault [1] - 27:15</p> <p>favor [1] - 27:24</p> <p>favorable [1] - 33:2</p> <p>FDA [18] - 4:18, 5:24, 9:14, 10:9, 10:20, 17:13, 19:12, 21:15, 24:3, 24:5, 26:13, 26:14, 26:18, 27:4, 34:20, 36:23, 39:21, 40:4</p> <p>FDA's [3] - 19:19, 24:9, 34:1</p> <p>Federal [6] - 6:12, 6:23, 9:8, 10:1, 10:3, 12:13</p> <p>field [8] - 4:19, 4:20, 5:5, 5:16, 5:17, 5:22, 10:17, 23:18</p> <p>figure [8] - 5:1, 11:17, 11:21, 17:2, 18:6, 28:17, 29:21, 36:4</p> <p>file [2] - 24:23, 35:24</p> <p>filed [12] - 12:6, 30:11, 31:15, 31:16, 31:18, 31:20, 31:21, 32:21, 32:23, 33:17, 33:18, 35:20</p> <p>filer [3] - 28:23, 31:4, 33:19</p> <p>filing [2] - 31:22, 32:17</p> <p>final [2] - 15:2, 19:17</p> <p>fine [1] - 14:16</p> <p>first [6] - 13:24, 15:24, 19:18, 28:23, 31:4, 32:17</p> <p>flesh [1] - 31:1</p> <p>flies [1] - 24:16</p> <p>float [2] - 17:10, 18:19</p> <p>floated [1] - 17:14</p> <p>flow [1] - 17:1</p> <p>folks [2] - 34:9, 36:15</p> <p>follow [1] - 13:25</p> <p>follow-on [1] - 13:25</p> <p>following [2] - 3:3, 29:25</p> <p>FOR [1] - 1:2</p> <p>forever [1] - 39:8</p>	<p>form [2] - 15:8, 16:8</p> <p>formulation [1] - 17:3</p> <p>forward [4] - 11:11, 34:2, 39:1, 40:1</p> <p>frame [1] - 37:2</p> <p>framework [1] - 33:17</p> <p>frankly [1] - 24:25</p> <p>free [1] - 38:3</p> <p>front [2] - 34:3, 37:5</p> <p>fully [1] - 18:15</p> <p>future [2] - 10:20, 14:20</p>	<p>23:21, 24:18</p> <p>head [1] - 37:11</p> <p>Healthcare [3] - 14:1, 20:18, 25:1</p> <p>healthcare [1] - 20:17</p> <p>hear [16] - 3:7, 3:13, 11:2, 13:19, 18:8, 18:23, 25:5, 25:8, 26:13, 26:25, 27:5, 27:6, 36:12, 39:19, 39:25, 40:4</p> <p>heard [3] - 32:10, 32:20, 39:21</p> <p>hearing [4] - 4:11, 15:22, 34:12, 38:19</p> <p>heaven [2] - 28:13, 36:6</p> <p>held [2] - 3:3, 20:7</p> <p>hello [1] - 4:1</p> <p>help [1] - 28:24</p> <p>high [1] - 17:10</p> <p>hold [2] - 16:12, 25:12</p> <p>holdings [1] - 6:22</p> <p>Honor [42] - 3:8, 3:14, 4:1, 4:18, 6:11, 8:3, 10:23, 11:14, 13:21, 13:23, 16:3, 16:11, 16:19, 18:5, 18:10, 19:3, 23:12, 23:20, 25:9, 25:15, 26:2, 26:23, 27:2, 27:23, 28:15, 28:16, 28:20, 29:6, 29:8, 30:13, 31:2, 31:14, 34:4, 34:17, 36:8, 38:8, 39:4, 39:23, 40:5, 40:6, 40:9, 40:12</p> <p>HONORABLE [1] - 1:16</p> <p>hope [2] - 27:19, 37:15</p> <p>hopeful [1] - 38:2</p> <p>hopefully [1] - 39:25</p> <p>hospital [1] - 15:11</p> <p>hypothesis [1] - 8:22</p> <p>hypothesized [1] - 9:3</p> <p>hypothetical [1] - 20:10</p>	<p>17:11, 27:10, 33:9</p> <p>importantly [1] - 15:15</p> <p>impromptu [1] - 25:21</p> <p>IN [2] - 1:1, 1:2</p> <p>in-person [1] - 28:9</p> <p>INC [2] - 1:4, 1:9</p> <p>inclination [1] - 37:24</p> <p>inconsistent [1] - 24:17</p> <p>independent [1] - 15:14</p> <p>inform [1] - 40:3</p> <p>infringe [11] - 5:7, 7:12, 13:3, 13:10, 14:8, 15:3, 16:22, 16:23, 18:3, 20:10, 20:11</p> <p>infringement [9] - 9:7, 10:3, 12:12, 13:17, 15:14, 17:7, 20:1, 20:8, 24:6</p> <p>infringes [1] - 11:8</p> <p>infringing [5] - 9:21, 9:25, 16:15, 17:6, 24:13</p> <p>initial [1] - 12:11</p> <p>injunction [1] - 17:25</p> <p>INNOVATION [1] - 1:5</p> <p>input [1] - 6:4</p> <p>instead [1] - 7:24</p> <p>insurance [1] - 9:20</p> <p>interested [1] - 27:16</p> <p>interesting [1] - 23:11</p> <p>interestingly [1] - 14:1</p> <p>internally [1] - 35:23</p> <p>interrupt [1] - 9:13</p> <p>invest [1] - 32:21</p> <p>invested [2] - 27:11, 30:20</p> <p>investigate [2] - 5:23, 5:24</p> <p>investigated</</p>
--	---	--	---	--

<p>27:13, 27:20, 28:4, 30:7, 32:15, 35:4, 35:14, 36:21, 38:1, 39:10, 39:11</p> <p>JEANNA [1] - 2:17</p> <p>Jeanna [1] - 3:17</p> <p>Jersey [1] - 2:3</p> <p>job [1] - 19:19</p> <p>judges [2] - 32:10, 35:8</p> <p>judgment [18] - 3:21, 8:19, 8:22, 14:11, 14:18, 15:15, 15:17, 15:19, 15:20, 16:8, 19:9, 24:14, 24:21, 24:23, 25:2, 25:20, 25:21, 26:5</p> <p>judicial [1] - 34:10</p> <p>jump [2] - 31:3, 31:7</p> <p>jumped [2] - 27:5, 35:23</p> <p>June [15] - 26:14, 26:18, 27:6, 28:9, 28:11, 34:18, 34:25, 36:3, 36:12, 37:7, 38:5, 38:6, 38:22, 39:18, 39:19</p> <p>jury [2] - 30:2, 34:6</p> <p>justice [1] - 29:16</p>	<p>least [2] - 7:22, 11:6</p> <p>leave [1] - 39:24</p> <p>leaves [1] - 9:18</p> <p>left [1] - 36:16</p> <p>legal [2] - 6:4, 10:21</p> <p>letter [3] - 23:13, 26:13, 31:1</p> <p>letting [1] - 13:8</p> <p>level [4] - 5:3, 11:8, 11:9, 32:6</p> <p>life [14] - 3:24, 4:7, 7:11, 8:7, 9:4, 9:24, 10:8, 10:12, 10:16, 13:10, 17:7, 19:18, 24:1</p> <p>likelihood [3] - 16:22, 17:10, 17:25</p> <p>likely [2] - 35:5, 35:11</p> <p>limited [2] - 20:14, 24:20</p> <p>line [4] - 14:2, 19:11, 19:24, 36:1</p> <p>literally [2] - 13:14, 19:17</p> <p>litigation [5] - 5:19, 14:13, 21:6, 33:21, 34:2</p> <p>live [2] - 27:18, 34:16</p> <p>LLC [2] - 1:5, 1:6</p> <p>LLP [5] - 1:19, 2:2, 2:6, 2:12, 2:16</p> <p>look [6] - 6:25, 8:24, 11:17, 12:9, 16:3, 21:8</p> <p>looked [2] - 4:11, 18:18</p> <p>looking [1] - 12:14</p> <p>looks [1] - 4:14</p> <p>lose [2] - 28:1, 30:6</p>	<p>Martin [2] - 3:9, 13:21</p> <p>MARTIN [1] - 2:7</p> <p>matter [3] - 30:9, 34:12, 36:1</p> <p>mean [28] - 6:18, 7:22, 8:17, 9:12, 9:13, 9:15, 11:2, 11:3, 11:10, 11:20, 12:1, 13:6, 17:22, 17:24, 18:11, 18:24, 20:6, 20:18, 22:9, 23:16, 25:5, 28:25, 29:16, 29:23, 32:5, 32:12, 32:16, 37:10</p> <p>means [1] - 31:24</p> <p>measured [1] - 3:23</p> <p>meet [3] - 5:3, 5:7, 19:20</p> <p>meets [1] - 19:23</p> <p>mentioned [1] - 30:5</p> <p>mercy [1] - 38:17</p> <p>merits [1] - 12:24</p> <p>method [2] - 15:7, 15:13</p> <p>might [3] - 5:20, 6:6, 6:10</p> <p>milligram [1] - 12:10</p> <p>millions [1] - 27:11</p> <p>minimum [1] - 15:16</p> <p>minor [6] - 34:23, 36:13, 36:14, 36:16, 36:17, 37:7</p> <p>misrepresentation [1] - 24:15</p> <p>moment [1] - 23:21</p> <p>Monday [1] - 1:13</p> <p>months [5] - 11:8, 19:17, 34:23, 34:24, 35:7</p> <p>MOORE [1] - 2:13</p> <p>Moore [1] - 3:17</p> <p>most [1] - 15:15</p> <p>motion [2] - 13:15, 19:9</p> <p>move [6] - 28:13, 34:2, 36:6, 38:24, 38:25, 40:1</p> <p>MR [61] - 3:8, 4:1, 4:17, 4:24, 5:9, 8:2, 8:15, 9:22, 10:19, 11:13, 13:13, 13:21, 16:11, 16:18, 18:2, 18:5, 18:10, 18:16, 19:2, 20:18, 21:4, 21:22, 21:25, 22:13, 22:17, 23:1, 23:8, 23:11, 23:20, 25:9, 25:15, 25:17, 26:2, 26:6, 26:11, 27:2, 28:7, 28:11, 28:16,</p>	<p>29:5, 29:20, 30:8, 30:13, 30:16, 30:24, 31:9, 31:13, 32:9, 32:18, 34:17, 36:8, 38:8, 38:9, 38:21, 39:4, 39:16, 39:23, 40:5, 40:6, 40:9, 40:12</p> <p>MS [1] - 3:14</p> <p>must [1] - 31:9</p>	<p>25:14, 27:9, 28:21, 29:3, 35:12, 37:2, 37:8, 38:14, 39:10</p> <p>OF [1] - 1:2</p> <p>offered [1] - 25:19</p> <p>Official [1] - 1:24</p> <p>old [2] - 13:11, 23:22</p> <p>once [1] - 9:18</p> <p>one [32] - 6:5, 8:13, 8:25, 10:16, 11:6, 11:18, 12:1, 15:6, 16:10, 16:13, 16:23, 17:12, 19:6, 19:17, 19:19, 20:20, 22:1, 26:20, 27:11, 29:24, 30:17, 30:20, 31:15, 33:14, 34:11, 36:3, 36:12, 36:20, 37:21, 38:12, 38:25</p> <p>opening [1] - 21:2</p> <p>operative [1] - 18:4</p> <p>opinion [1] - 15:4</p> <p>opposed [1] - 9:15</p> <p>options [1] - 27:25</p> <p>order [4] - 9:3, 9:24, 36:4, 39:13</p> <p>originally [1] - 28:19</p> <p>ought [1] - 36:2</p> <p>out-of-spec [3] - 12:17, 19:7, 19:17</p> <p>outright [1] - 34:25</p> <p>overlap [4] - 21:15, 21:24, 22:11, 36:22</p> <p>overlapped [2] - 21:13, 22:10</p> <p>own [1] - 18:7</p> <p>owner [3] - 14:7, 20:7, 20:9</p>
<p>K</p>				
<p>keep [3] - 10:17, 14:13, 30:8</p> <p>kind [8] - 7:16, 7:21, 7:24, 9:19, 17:23, 31:21, 32:6, 33:17</p> <p>KIRKLAND [1] - 2:16</p> <p>Kirkland [2] - 3:18, 4:2</p>				
<p>L</p>	<p>M</p>			<p>P</p>
<p>language [6] - 6:21, 20:13, 20:20, 24:24, 25:1, 25:3</p> <p>last [6] - 7:23, 15:22, 25:17, 27:8, 27:23, 28:20</p> <p>late [1] - 35:25</p> <p>launch [3] - 15:1, 23:23, 39:1</p> <p>law [9] - 11:23, 12:2, 14:18, 14:23, 16:2, 16:4, 19:11, 22:21, 24:16</p> <p>Lawrence [1] - 3:11</p> <p>lead [1] - 7:3</p> <p>learn [2] - 4:20, 4:22</p> <p>learned [4] - 4:7, 5:10, 5:20, 8:7</p>	<p>main [1] - 22:7</p> <p>maintain [1] - 10:11</p> <p>maintained [1] - 8:7</p> <p>maintaining [1] - 8:8</p> <p>major [3] - 34:22, 36:13, 36:17</p> <p>mandated [1] - 7:23</p> <p>manufacturer's [1] - 14:8</p> <p>market [18] - 6:14, 7:5, 7:24, 8:12, 11:4, 11:12, 11:24, 12:4, 12:20, 13:1, 13:16, 14:25, 15:1, 16:20, 20:2, 20:22, 21:8, 33:20</p> <p>marketed [1] - 20:9</p> <p>Markmans [1] - 30:3</p>	<p>MOORE [1] - 2:13</p> <p>Moore [1] - 3:17</p> <p>most [1] - 15:15</p> <p>motion [2] - 13:15, 19:9</p> <p>move [6] - 28:13, 34:2, 36:6, 38:24, 38:25, 40:1</p> <p>MR [61] - 3:8, 4:1, 4:17, 4:24, 5:9, 8:2, 8:15, 9:22, 10:19, 11:13, 13:13, 13:21, 16:11, 16:18, 18:2, 18:5, 18:10, 18:16, 19:2, 20:18, 21:4, 21:22, 21:25, 22:13, 22:17, 23:1, 23:8, 23:11, 23:20, 25:9, 25:15, 25:17, 26:2, 26:6, 26:11, 27:2, 28:7, 28:11, 28:16,</p>	<p>29:5, 29:20, 30:8, 30:13, 30:16, 30:24, 31:9, 31:13, 32:9, 32:18, 34:17, 36:8, 38:8, 38:9, 38:21, 39:4, 39:16, 39:23, 40:5, 40:6, 40:9, 40:12</p> <p>MS [1] - 3:14</p> <p>must [1] - 31:9</p>	<p>25:14, 27:9, 28:21, 29:3, 35:12, 37:2, 37:8, 38:14, 39:10</p> <p>OF [1] - 1:2</p> <p>offered [1] - 25:19</p> <p>Official [1] - 1:24</p> <p>old [2] - 13:11, 23:22</p> <p>once [1] - 9:18</p> <p>one [32] - 6:5, 8:13, 8:25, 10:16, 11:6, 11:18, 12:1, 15:6, 16:10, 16:13, 16:23, 17:12, 19:6, 19:17, 19:19, 20:20, 22:1, 26:20, 27:11, 29:24, 30:17, 30:20, 31:15, 33:14, 34:11, 36:3, 36:12, 36:20, 37:21, 38:12, 38:25</p> <p>opening [1] - 21:2</p> <p>operative [1] - 18:4</p> <p>opinion [1] - 15:4</p> <p>opposed [1] - 9:15</p> <p>options [1] - 27:25</p> <p>order [4] - 9:3, 9:24, 36:4, 39:13</p> <p>originally [1] - 28:19</p> <p>ought [1] - 36:2</p> <p>out-of-spec [3] - 12:17, 19:7, 19:17</p> <p>outright [1] - 34:25</p> <p>overlap [4] - 21:15, 21:24, 22:11, 36:22</p> <p>overlapped [2] - 21:13, 22:10</p> <p>own [1] - 18:7</p> <p>owner [3] - 14:7, 20:7, 20:9</p>
<p>language [6] - 6:21, 20:13, 20:20, 24:24, 25:1, 25:3</p> <p>last [6] - 7:23, 15:22, 25:17, 27:8, 27:23, 28:20</p> <p>late [1] - 35:25</p> <p>launch [3] - 15:1, 23:23, 39:1</p> <p>law [9] - 11:23, 12:2, 14:18, 14:23, 16:2, 16:4, 19:11, 22:21, 24:16</p> <p>Lawrence [1] - 3:11</p> <p>lead [1] - 7:3</p> <p>learn [2] - 4:20, 4:22</p> <p>learned [4] - 4:7, 5:10, 5:20, 8:7</p>	<p>main [1] - 22:7</p> <p>maintain [1] - 10:11</p> <p>maintained [1] - 8:7</p> <p>maintaining [1] - 8:8</p> <p>major [3] - 34:22, 36:13, 36:17</p> <p>mandated [1] - 7:23</p> <p>manufacturer's [1] - 14:8</p> <p>market [18] - 6:14, 7:5, 7:24, 8:12, 11:4, 11:12, 11:24, 12:4, 12:20, 13:1, 13:16, 14:25, 15:1, 16:20, 20:2, 20:22, 21:8, 33:20</p> <p>marketed [1] - 20:9</p> <p>Markmans [1] - 30:3</p>	<p>MOORE [1] - 2:13</p> <p>Moore [1] - 3:17</p> <p>most [1] - 15:15</p> <p>motion [2] - 13:15, 19:9</p> <p>move [6] - 28:13, 34:2, 36:6, 38:24, 38:25, 40:1</p> <p>MR [61] - 3:8, 4:1, 4:17, 4:24, 5:9, 8:2, 8:15, 9:22, 10:19, 11:13, 13:13, 13:21, 16:11, 16:18, 18:2, 18:5, 18:10, 18:16, 19:2, 20:18, 21:4, 21:22, 21:25, 22:13, 22:17, 23:1, 23:8, 23:11, 23:20, 25:9, 25:15, 25:17, 26:2, 26:6, 26:11, 27:2, 28:7, 28:11, 28:16,</p>	<p>29:5, 29:20, 30:8, 30:13, 30:16, 30:24, 31:9, 31:13, 32:9, 32:18, 34:17, 36:8, 38:8, 38:9, 38:21, 39:4, 39:16, 39:23, 40:5, 40:6, 40:9, 40:12</p> <p>MS [1] - 3:14</p> <p>must [1] - 31:9</p>	<p>25:14, 27:9, 28:21, 29:3, 35:12, 37:2, 37:8, 38:14, 39:10</p> <p>OF [1] - 1:2</p> <p>offered [1] - 25:19</p> <p>Official [1] - 1:24</p> <p>old [2] - 13:11, 23:22</p> <p>once [1] - 9:18</p> <p>one [32] - 6:5, 8:13, 8:25, 10:16, 11:6, 11:18, 12:1, 15:6, 16:10, 16:13, 16:23, 17:12, 19:6, 19:17, 19:19, 20:20, 22:1, 26:20, 27:11, 29:24, 30:17, 30:20, 31:15, 33:14, 34:11, 36:3, 36:12, 36:20, 37:21, 38:12, 38:25</p> <p>opening [1] - 21:2</p> <p>operative [1] - 18:4</p> <p>opinion [1] - 15:4</p> <p>opposed [1] - 9:15</p> <p>options [1] - 27:25</p> <p>order [4] - 9:3, 9:24, 36:4, 39:13</p> <p>originally [1] - 28:19</p> <p>ought [1] - 36:2</p> <p>out-of-spec [3] - 12:17, 19:7, 19:17</p> <p>outright [1] - 34:25</p> <p>overlap [4] - 21:15, 21:24, 22:11, 36:22</p> <p>overlapped [2] - 21:13, 22:10</p> <p>own [1] - 18:7</p> <p>owner [3] - 14:7, 20:7, 20:9</p>
<p>L</p>	<p>M</p>		<p>N</p>	<p>P</p>
<p>language [6] - 6:21, 20:13, 20:20, 24:24, 25:1, 25:3</p> <p>last [6] - 7:23, 15:22, 25:17, 27:8, 27:23, 28:20</p> <p>late [1] - 35:25</p> <p>launch [3] - 15:1, 23:23, 39:1</p> <p>law [9] - 11:23, 12:2, 14:18, 14:23, 16:2, 16:4, 19:11, 22:21, 24:16</p> <p>Lawrence [1] - 3:11</p> <p>lead [1] - 7:3</p> <p>learn [2] - 4:20, 4:22</p> <p>learned [4] - 4:7, 5:10, 5:20, 8:7</p>	<p>main [1] - 22:7</p> <p>maintain [1] - 10:11</p> <p>maintained [1] - 8:7</p> <p>maintaining [1] - 8:8</p> <p>major [3] - 34:22, 36:13, 36:17</p> <p>mandated [1] - 7:23</p> <p>manufacturer's [1] - 14:8</p> <p>market [18] - 6:14, 7:5, 7:24, 8:12, 11:4, 11:12, 11:24, 12:4, 12:20, 13:1, 13:16, 14:25, 15:1, 16:20, 20:2, 20:22, 21:8, 33:20</p> <p>marketed [1] - 20:9</p> <p>Markmans [1] - 30:3</p>	<p>MOORE [1] - 2:13</p> <p>Moore [1] - 3:17</p> <p>most [1] - 15:15</p> <p>motion [2] - 13:15, 19:9</p> <p>move [6] - 28:13, 34:2, 36:6, 38:24, 38:25, 40:1</p> <p>MR [61] - 3:8, 4:1, 4:17, 4:24, 5:9, 8:2, 8:15, 9:22, 10:19, 11:13, 13:13, 13:21, 16:11, 16:18, 18:2, 18:5, 18:10, 18:16, 19:2, 20:18, 21:4, 21:22, 21:25, 22:13, 22:17, 23:1, 23:8, 23:11, 23:20, 25:9, 25:15, 25:17, 26:2, 26:6, 26:11, 27:2, 28:7, 28:11, 28:16,</p>	<p>29:5, 29:20, 30:8, 30:13, 30:16, 30:24, 31:9, 31:13, 32:9, 32:18, 34:17, 36:8, 38:8, 38:9, 38:21, 39:4, 39:16, 39:23, 40:5, 40:6, 40:9, 40:12</p> <p>MS [1] - 3:14</p> <p>must [1] - 31:9</p>	<p>25:14, 27:9, 28:21, 29:3, 35:12, 37:2, 37:8, 38:14, 39:10</p> <p>OF [1] - 1:2</p> <p>offered [1] - 25:19</p> <p>Official [1] - 1:24</p> <p>old [2] - 13:11, 23:22</p> <p>once [1] - 9:18</p> <p>one [32] - 6:5, 8:13, 8:25, 10:16, 11:6, 11:18, 12:1, 15:6, 16:10, 16:13, 16:23, 17:12, 19:6, 19:17, 19:19, 20:20, 22:1, 26:20, 27:11, 29:24, 30:17, 30:20, 31:15, 33:14, 34:11, 36:3, 36:12, 36:20, 37:21, 38:12, 38:25</p> <p>opening [1] - 21:2</p> <p>operative [1] - 18:4</p> <p>opinion [1] - 15:4</p> <p>opposed [1] - 9:15</p> <p>options [1] - 27:25</p> <p>order [4] - 9:3, 9:24, 36:4, 39:13</p> <p>originally [1] - 28:19</p> <p>ought [1] - 36:2</p> <p>out-of-spec [3] - 12:17, 19:7, 19:17</p> <p>outright [1] - 34:25</p> <p>overlap [4] - 21:15, 21:24, 22:11, 36:22</p> <p>overlapped [2] - 21:13, 22:10</p> <p>own [1] - 18:7</p> <p>owner [3] - 14:7, 20:7, 20:9</p>
<p>L</p>	<p>M</p>		<p>O</p>	<p>P</p>
<p>language [6] - 6:21, 20:13, 20:20, 24:24, 25:1, 25:3</p> <p>last [6] - 7:23, 15:22, 25:17, 27:8, 27:23, 28:20</p> <p>late [1] - 35:25</p> <p>launch [3] - 15:1, 23:23, 39:1</p> <p>law [9] - 11:23, 12:2, 14:18, 14:23, 16:2, 16:4, 19:11, 22:21, 24:16</p> <p>Lawrence [1] - 3:11</p> <p>lead [1] - 7:3</p> <p>learn [2] - 4:20, 4:22</p> <p>learned [4] - 4:7, 5:10, 5:20, 8:7</p>	<p>main [1] - 22:7</p> <p>maintain [1] - 10:11</p> <p>maintained [1] - 8:7</p> <p>maintaining [1] - 8:8</p> <p>major [3] - 34:22, 36:13, 36:17</p> <p>mandated [1] - 7:23</p> <p>manufacturer's [1] - 14:8</p> <p>market [18] - 6:14, 7:5, 7:24, 8:12, 11:4, 11:12, 11:24, 12:4, 12:20, 13:1, 13:16, 14:25, 15:1, 16:20, 20:2, 20:22, 21:8, 33:20</p> <p>marketed [1] - 20:9</p> <p>Markmans [1] - 30:3</p>	<p>MOORE [1] - 2:13</p> <p>Moore [1] - 3:17</p> <p>most [1] - 15:15</p> <p>motion [2] - 13:15, 19:9</p> <p>move [6] - 28:13, 34:2, 36:6, 38:24, 38:25, 40:1</p> <p>MR [61] - 3:8, 4:1, 4:17, 4:24, 5:9, 8:2, 8:15, 9:22, 10:19, 11:13, 13:13, 13:21, 16:11, 16:18, 18:2, 18:5, 18:10, 18:16, 19:2, 20:18, 21:4, 21:22, 21:25, 22:13, 22:17, 23:1, 23:8, 23:11, 23:20, 25:9, 25:15, 25:17, 26:2, 26:6, 26:11, 27:2, 28:7, 28:11, 28:16,</p>	<p>29:5, 29:20, 30:8, 30:13, 30:16, 30:24, 31:9, 31:13, 32:9, 32:18, 34:17, 36:8, 38:8, 38:9, 38:21, 39:4, 39:16, 39:23, 40:5, 40:6, 40:9, 40:12</p> <p>MS [1] - 3:14</p> <p>must [1] - 31:9</p>	<p>25:14, 27:9, 28:21, 29:3, 35:12, 37:2, 37:8, 38:14, 39:10</p> <p>OF [1] - 1:2</p> <p>offered [1] - 25:19</p> <p>Official [1] - 1:24</p> <p>old [2] - 13:11, 23:22</p> <p>once [1] - 9:18</p> <p>one [32] - 6:5, 8:13, 8:25, 10:16, 11:6, 11:18, 12:1, 15:6, 16:10, 16:13, 16:23, 17:12, 19:6, 19:17, 19:19, 20:20, 22:1, 26:20, 27:11, 29:24, 30:17, 30:20, 31:15, 33:14, 34:11, 36:3, 36:12, 36:20, 37:21, 38:12, 38:25</p> <p>opening [1] - 21:2</p> <p>operative [1] - 18:4</p> <p>opinion [1] - 15:4</p> <p>opposed [1] - 9:15</p> <p>options [1] - 27:25</p> <p>order [4] - 9:3, 9:24, 36:4, 39:13</p> <p>originally [1] - 28:19</p> <p>ought [1] - 36:2</p> <p>out-of-spec [3] - 12:17, 19:7, 19:17</p> <p>outright [1] - 34:25</p> <p>overlap [4] - 21:15</p>

<p>parties [7] - 9:2, 22:21, 27:22, 32:11, 32:12, 39:20, 40:3</p> <p>parts [1] - 33:8</p> <p>party [1] - 31:7</p> <p>passive [1] - 9:16</p> <p>patent [11] - 3:25, 5:19, 13:11, 14:7, 20:7, 20:8, 23:22, 35:13, 35:14, 36:21, 39:10</p> <p>patented [1] - 22:5</p> <p>patents [1] - 39:11</p> <p>paths [1] - 31:25</p> <p>pathway [1] - 33:21</p> <p>patient [3] - 5:18, 5:25, 6:5</p> <p>Pennington [2] - 20:19, 21:5</p> <p>Pennsylvania [1] - 2:8</p> <p>people [1] - 33:5</p> <p>perhaps [1] - 29:7</p> <p>periodic [1] - 7:17</p> <p>periodically [1] - 11:16</p> <p>person [2] - 28:9, 38:20</p> <p>perspective [1] - 36:11</p> <p>pH [18] - 3:23, 5:3, 7:10, 8:6, 9:1, 9:2, 9:20, 11:8, 11:9, 15:8, 16:24, 16:25, 17:1, 17:8, 19:13, 22:3, 22:14, 23:24</p> <p>PHARMACEUTICAL [2] - 1:4, 1:9</p> <p>pharmaceutical [1] - 30:1</p> <p>Philadelphia [1] - 2:8</p> <p>phone [2] - 3:11, 28:20</p> <p>PI [1] - 39:2</p> <p>place [2] - 37:4, 37:15</p> <p>plaintiff [3] - 3:9, 9:3, 13:20</p> <p>Plaintiffs [2] - 1:7, 2:9</p> <p>plaintiffs [4] - 3:7, 25:8, 40:8, 40:10</p> <p>players [1] - 32:23</p> <p>plenty [1] - 36:15</p> <p>point [25] - 3:24, 7:20, 8:15, 11:12, 11:13, 11:23, 11:25, 12:22, 13:11, 14:3, 15:21, 16:14, 19:2, 19:8, 19:12, 21:11, 22:7, 22:18, 23:2, 23:11, 24:2, 26:4, 26:24, 33:13, 33:14</p>	<p>pointed [2] - 29:6, 31:8</p> <p>points [1] - 27:8</p> <p>position [2] - 29:11, 35:4</p> <p>possible [1] - 28:1</p> <p>posture [1] - 33:2</p> <p>potentially [2] - 37:6, 37:11</p> <p>POTTER [1] - 2:12</p> <p>Potter [2] - 3:15, 3:16</p> <p>practical [1] - 36:1</p> <p>precluded [1] - 7:19</p> <p>predict [1] - 14:19</p> <p>predictions [1] - 34:19</p> <p>preferably [1] - 33:22</p> <p>prejudice [1] - 31:3</p> <p>premise [2] - 6:11, 10:22</p> <p>prepare [1] - 39:2</p> <p>prepared [4] - 38:13, 38:14, 38:24, 39:2</p> <p>presented [1] - 22:1</p> <p>presume [3] - 6:15, 6:24, 12:3</p> <p>presumes [2] - 22:6, 22:19</p> <p>presuming [4] - 10:7, 22:19, 22:22, 22:23</p> <p>presumption [5] - 9:9, 10:2, 10:4, 23:4, 23:5</p> <p>presumptions [1] - 8:16</p> <p>pretrial [3] - 27:22, 36:4, 39:13</p> <p>prevail [1] - 31:4</p> <p>primarily [1] - 25:18</p> <p>Princeton [1] - 2:3</p> <p>priority [1] - 30:10</p> <p>privilege [1] - 32:17</p> <p>problem [3] - 17:8, 17:15, 25:18</p> <p>procedural [1] - 15:24</p> <p>proceed [2] - 27:23, 33:18</p> <p>process [4] - 15:19, 17:13, 25:20, 25:23</p> <p>product [51] - 3:23, 3:24, 5:8, 5:11, 6:14, 7:5, 7:8, 7:11, 7:15, 7:18, 7:20, 7:25, 8:6, 9:5, 9:17, 9:21, 10:17, 11:4, 11:7, 11:24, 12:19, 13:1, 13:9, 13:16, 14:8, 15:9, 15:12, 16:15, 16:20, 16:25, 17:10, 17:20, 19:23, 20:2, 20:10, 20:21, 21:7,</p>	<p>21:18, 22:2, 22:4, 23:25, 24:11, 24:19, 26:16, 29:12, 29:19, 35:23, 36:2, 39:7</p> <p>PRODUCTS [1] - 1:5</p> <p>products [2] - 11:15, 23:23</p> <p>promising [1] - 38:16</p> <p>proof [1] - 17:9</p> <p>protect [2] - 32:24, 33:6</p> <p>prove [2] - 16:16, 16:19</p> <p>provide [1] - 33:10</p> <p>provided [1] - 24:4</p> <p>purpose [1] - 10:6</p> <p>put [10] - 4:13, 9:19, 13:6, 13:7, 19:8, 23:21, 28:2, 36:4, 37:15, 37:21</p>	<p>reconvene [1] - 26:17</p> <p>record [2] - 4:13, 14:3</p> <p>recourse [1] - 32:16</p> <p>Regent [3] - 30:18, 31:21, 33:7</p> <p>regs [2] - 4:13, 4:17</p> <p>regular [2] - 13:11, 23:22</p> <p>regulatory [3] - 4:18, 8:3, 31:25</p> <p>rehash [1] - 26:4</p> <p>reiterate [1] - 27:8</p> <p>rejigger [1] - 35:21</p> <p>related [1] - 27:4</p> <p>release [10] - 4:6, 8:6, 9:9, 9:13, 9:16, 10:11, 10:15, 15:9, 19:13, 23:9</p> <p>released [1] - 22:4</p> <p>releasing [1] - 10:6</p> <p>relief [3] - 13:5, 26:23, 37:6</p> <p>rely [2] - 14:7, 14:19</p> <p>relying [1] - 16:5</p> <p>removal [1] - 7:23</p> <p>remove [2] - 17:8, 37:20</p> <p>repeat [1] - 18:15</p> <p>report [2] - 5:16, 24:19</p> <p>Reporter [1] - 1:24</p> <p>reports [1] - 5:5</p> <p>representation [2] - 15:24, 16:2</p> <p>representations [1] - 15:22</p> <p>representative [3] - 11:19, 11:20, 11:22</p> <p>represented [1] - 25:24</p> <p>request [1] - 3:21</p> <p>requested [1] - 19:21</p> <p>required [2] - 8:25, 9:1</p> <p>requirement [1] - 23:13</p> <p>requirements [2] - 23:6, 23:9</p> <p>requires [2] - 22:19, 25:1</p> <p>reserve [1] - 17:17</p> <p>resolved [1] - 20:1</p> <p>respect [1] - 14:21</p> <p>respond [2] - 18:9, 30:14</p> <p>responding [1] - 17:23</p> <p>response [4] - 5:9, 10:19, 19:7, 19:16</p> <p>restriction [1] - 19:13</p> <p>rests [1] - 6:11</p>	<p>result [1] - 16:5</p> <p>retrial [1] - 29:24</p> <p>retrials [1] - 29:24</p> <p>reveals [1] - 7:17</p> <p>reverse [1] - 20:20</p> <p>review [3] - 21:19, 24:5, 24:6</p> <p>RHOAD [1] - 2:3</p> <p>Rhoad [1] - 3:10</p> <p>rises [3] - 9:20, 20:12, 21:3</p> <p>Robert [1] - 3:10</p> <p>ROBERT [1] - 2:3</p> <p>roll [1] - 26:20</p> <p>room [1] - 12:25</p> <p>round [1] - 14:12</p> <p>rule [1] - 15:19</p> <p>run [1] - 7:15</p> <p>running [1] - 35:25</p>
S				
<p>safe [1] - 40:14</p> <p>safety [5] - 5:19, 5:25, 6:5, 7:21, 7:24</p> <p>sale [1] - 9:15</p> <p>sales [1] - 7:3</p> <p>Sandoz [2] - 31:16, 33:1</p> <p>satisfaction [1] - 21:17</p> <p>satisfied [1] - 10:10</p> <p>saw [1] - 19:16</p> <p>scenario [9] - 4:24, 4:25, 6:2, 10:1, 10:21, 11:20, 21:14, 34:7</p> <p>scenarios [1] - 5:18</p> <p>schedule [2] - 26:8, 38:17</p> <p>scheduled [2] - 37:9</p> <p>scheduling [1] - 25:18</p> <p>schedulingwise [1] - 32:13</p> <p>second [3] - 7:9, 14:12, 16:2</p> <p>Section [1] - 20:8</p> <p>section [1] - 13:14</p> <p>see [5] - 28:25, 30:3, 33:7, 36:3, 38:5</p> <p>seeing [1] - 19:7</p> <p>seek [1] - 4:15</p> <p>seeking [3] - 5:4, 8:5</p> <p>seem [1] - 16:16</p> <p>sell [14] - 3:23, 4:3, 4:12, 4:14, 4:15, 5:4, 5:12, 7:13, 8:6, 8:9, 17:5, 17:17, 23:23</p> <p>selling [2] - 7:20, 17:19</p>				

<p>September [7] - 28:21, 29:1, 29:24, 30:3, 30:4, 37:8, 38:14</p> <p>set [8] - 18:20, 26:18, 27:13, 29:13, 32:7, 35:16, 38:10, 40:2</p> <p>setting [1] - 6:13</p> <p>settle [1] - 38:3</p> <p>settled [3] - 30:25, 31:8, 32:1</p> <p>settlement [2] - 31:10, 32:19</p> <p>seven [1] - 9:1</p> <p>several [1] - 34:23</p> <p>sham [1] - 21:6</p> <p>shelf [13] - 3:24, 4:7, 7:11, 8:7, 9:4, 9:19, 10:12, 10:16, 11:8, 11:16, 13:10, 17:7, 19:18</p> <p>short [1] - 13:14</p> <p>show [3] - 16:14, 16:16, 16:21</p> <p>shows [1] - 10:10</p> <p>sides [3] - 29:16, 29:22, 38:12</p> <p>significant [3] - 14:6, 30:1, 36:17</p> <p>silent [1] - 23:13</p> <p>similar [1] - 30:11</p> <p>single [1] - 11:11</p> <p>sit [1] - 8:17</p> <p>sitting [1] - 11:7</p> <p>situation [6] - 8:25, 12:25, 27:10, 27:16, 37:10, 37:20</p> <p>six [1] - 30:2</p> <p>SJ [1] - 13:15</p> <p>sold [6] - 5:11, 7:15, 8:1, 9:21, 24:11</p> <p>solely [1] - 25:2</p> <p>solution [1] - 25:20</p> <p>sometimes [2] - 33:15, 33:16</p> <p>soon [2] - 28:11, 40:4</p> <p>sorry [4] - 9:12, 12:7, 26:2, 29:20</p> <p>Sorry [1] - 21:22</p> <p>sort [1] - 35:1</p> <p>sought [3] - 4:5, 5:12, 10:8</p> <p>sounded [1] - 29:7</p> <p>sounds [1] - 8:14</p> <p>spec [27] - 4:6, 5:3, 5:7, 6:12, 6:16, 7:18, 8:6, 9:5, 9:6, 9:10, 9:24, 9:25, 10:6, 10:11, 10:15, 11:10, 12:3, 12:5, 12:11, 12:16, 12:17, 12:20,</p>	<p>13:2, 14:9, 17:5, 19:7, 19:17</p> <p>specification [19] - 4:4, 9:1, 10:12, 10:24, 19:11, 19:13, 19:21, 19:25, 20:2, 20:13, 20:23, 21:3, 21:9, 21:12, 22:6, 22:20, 25:3, 35:22</p> <p>specifications [2] - 19:5, 22:24</p> <p>specified [1] - 20:11</p> <p>speculating [1] - 6:3</p> <p>speculative [5] - 5:14, 6:8, 16:17, 16:18, 18:17</p> <p>spell [1] - 29:15</p> <p>spite [1] - 14:9</p> <p>square [2] - 20:5, 20:6</p> <p>squares [1] - 21:11</p> <p>squeeze [1] - 38:16</p> <p>stability [11] - 4:6, 5:3, 7:10, 10:12, 11:15, 19:14, 22:24, 23:6, 23:13, 23:14, 35:22</p> <p>stacked [1] - 31:20</p> <p>standard [2] - 5:23, 18:1</p> <p>standpoint [1] - 27:18</p> <p>starting [2] - 14:2, 28:9</p> <p>state [1] - 13:18</p> <p>statement [4] - 20:6, 21:2, 22:14</p> <p>STATES [1] - 1:1</p> <p>stay [10] - 9:24, 25:10, 25:13, 26:22, 29:3, 33:23, 33:25, 35:17, 36:16, 40:13</p> <p>step [1] - 31:14</p> <p>steps [1] - 26:10</p> <p>STERILE [1] - 1:5</p> <p>still [6] - 7:19, 29:11, 33:2, 33:9, 36:18</p> <p>stop [1] - 38:25</p> <p>story [2] - 9:13, 14:4</p> <p>straight [1] - 14:24</p> <p>straight-up [1] - 14:24</p> <p>strength [4] - 30:10, 31:15, 31:16, 31:18</p> <p>strikes [1] - 5:5</p> <p>stuff [2] - 5:23, 23:21</p> <p>submissions [1] - 27:22</p> <p>subsequent [3] - 6:22, 12:18, 24:25</p> <p>sue [1] - 11:25</p> <p>sufficient [2] - 15:5, 24:20</p> <p>suggest [4] - 6:8,</p>	<p>12:15, 14:3, 20:22</p> <p>suggested [2] - 18:19, 28:22</p> <p>suggesting [2] - 18:11, 18:18</p> <p>suggestion [3] - 7:2, 26:17, 36:10</p> <p>summarized [1] - 6:19</p> <p>summary [20] - 3:21, 7:22, 8:19, 8:21, 14:10, 14:18, 15:15, 15:17, 15:19, 15:20, 16:8, 19:9, 24:13, 24:21, 24:23, 25:1, 25:20, 25:21, 26:5, 29:17</p> <p>Sunday [1] - 39:18</p> <p>Sunovion [2] - 17:19, 21:12</p> <p>sweat [1] - 28:2</p> <p>system [1] - 34:11</p>	<p>32:5, 32:10, 34:8, 37:22, 38:10, 38:22, 39:15, 39:18, 39:24, 40:7, 40:11, 40:13</p> <p>theory [11] - 6:10, 10:22, 12:23, 12:25, 18:13, 21:25, 22:2, 22:18, 22:19</p> <p>therefore [1] - 9:7</p> <p>they've [14] - 6:25, 7:5, 10:10, 13:4, 13:5, 15:1, 18:16, 18:18, 18:19, 21:25, 30:5, 35:21, 39:7</p> <p>thinking [1] - 27:17</p> <p>thinks [1] - 24:3</p> <p>third [1] - 16:5</p> <p>threatening [1] - 23:22</p> <p>three [4] - 15:21, 16:23, 17:13, 36:12</p> <p>throughout [1] - 9:24</p> <p>thumbs [2] - 26:14, 26:15</p> <p>timing [2] - 27:18, 36:11</p> <p>today [3] - 3:16, 3:17, 8:17</p> <p>together [1] - 26:21</p> <p>tomorrow [1] - 35:7</p> <p>took [1] - 7:1</p> <p>top [1] - 16:24</p> <p>total [1] - 36:22</p> <p>totality [1] - 6:20</p> <p>totally [1] - 21:13</p> <p>towards [2] - 17:7, 33:18</p> <p>transcript [1] - 4:11</p> <p>translator [1] - 34:13</p> <p>travel [1] - 28:17</p> <p>trial [40] - 24:8, 25:6, 25:19, 26:18, 27:9, 27:12, 27:16, 27:20, 27:21, 28:1, 28:4, 28:6, 28:10, 28:15, 28:20, 28:25, 29:8, 29:13, 29:18, 29:23, 29:25, 30:2, 30:4, 30:6, 30:9, 30:22, 32:7, 32:22, 35:3, 35:11, 35:12, 35:13, 35:16, 36:5, 37:4, 37:8, 37:9, 37:15, 39:9, 39:11</p> <p>trials [7] - 27:18, 28:9, 33:14, 34:5, 37:14, 37:25, 39:9</p> <p>tried [1] - 17:2</p> <p>TRO/PI [1] - 37:10</p> <p>true [1] - 22:15</p>	<p>try [7] - 5:13, 17:16, 35:7, 37:16, 38:14, 38:15, 38:19</p> <p>trying [15] - 5:1, 5:10, 19:3, 29:13, 29:21, 29:22, 32:5, 32:7, 32:24, 33:6, 33:12, 34:2, 36:6, 36:23, 39:6</p> <p>turns [3] - 5:2, 25:2, 37:18</p> <p>two [3] - 29:23, 33:19, 39:9</p> <p>Tyco [8] - 13:25, 20:6, 20:17, 20:18, 21:5, 24:17, 25:1</p> <p>type [3] - 14:5, 31:22, 37:6</p>
U				
<p>U.S.D.C.J [1] - 1:16</p> <p>ultimately [1] - 17:20</p> <p>unapproved [1] - 29:18</p> <p>under [7] - 5:5, 13:4, 17:19, 20:8, 20:14, 29:13, 37:23</p> <p>understood [3] - 17:12, 23:17, 40:6</p> <p>unexpected [1] - 5:17</p> <p>unit [1] - 15:8</p> <p>UNITED [1] - 1:1</p> <p>unless [1] - 10:10</p> <p>unlike [1] - 35:5</p> <p>unquote [1] - 20:11</p> <p>unreasonable [1] - 20:7</p> <p>unusual [2] - 17:1, 37:13</p> <p>up [17] - 5:16, 8:18, 11:4, 14:10, 14:24, 17:1, 17:6, 24:12, 25:14, 26:14, 31:14, 31:20, 33:5, 38:3, 38:10, 39:11, 40:2</p> <p>urgent [1] - 29:7</p>				
V				
<p>Valerie [1] - 1:24</p> <p>value [1] - 33:10</p> <p>various [1] - 35:8</p> <p>verge [1] - 13:8</p> <p>viable [1] - 13:13</p> <p>vial [2] - 11:7, 11:12</p> <p>view [3] - 14:17, 14:22, 24:9</p> <p>virtual [1] - 38:19</p> <p>virus [1] - 27:15</p>				

vs ^[1] - 1:8
W
WACKER ^[1] - 2:17 Wacker ^[1] - 3:18 wait ^[4] - 25:12, 31:6, 36:2, 38:4 waiting ^[2] - 27:20, 28:4 wants ^[1] - 32:14 Waxman ^[6] - 13:7, 14:23, 16:20, 17:24, 23:21, 24:18 week ^[1] - 29:25 whatsoever ^[1] - 37:19 whereas ^[1] - 10:15 whole ^[4] - 5:2, 10:22, 14:4, 21:25 wholly ^[1] - 18:16 willing ^[1] - 35:5 Wilmington ^[1] - 1:12 win ^[1] - 24:2 witness ^[1] - 34:16 won ^[1] - 38:23 wondered ^[1] - 29:8 wording ^[1] - 24:17 words ^[3] - 9:16, 22:10, 30:17 works ^[1] - 29:22 worried ^[1] - 9:14 worth ^[1] - 26:3
Y
year ^[2] - 38:15 York ^[2] - 2:18 yourself ^[1] - 39:2
Z
Zoom ^[3] - 27:18, 34:5, 34:9

EXHIBIT C

REDACTED

EXHIBIT D

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

PAR PHARMACEUTICAL, INC.,)	
PAR STERILE PRODUCTS, LLC, and)	
ENDO PAR INNOVATION)	
COMPANY, LLC,)	
)	C.A. No. 18-823-CFC
Plaintiffs,)	
)	
v.)	
)	
EAGLE PHARMACEUTICALS INC.,)	
)	
Defendant.)	

**LETTER TO THE HONORABLE COLM F. CONNOLLY
FROM BINDU A. PALAPURA, ESQUIRE**

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June 24, 2020

VIA ELECTRONIC FILING

The Honorable Colm F. Connolly
United States District Judge
J. Caleb Boggs Federal Building
844 N. King Street
Unit 31, Room 4124
Wilmington, DE 19801-3555



Re: *Par Pharm., Inc. v. Eagle Pharm., Inc.*, C.A. No. 18-823-CFC

Dear Judge Connolly:

This firm, together with Kirkland & Ellis LLP, represents Defendant Eagle Pharmaceuticals, Inc. (“Eagle”) in the above-captioned matter. We write to apprise the Court of the status of Eagle’s Abbreviated New Drug Application (“ANDA”) at issue in this litigation, as requested by the Court at the conclusion of the May 18, 2020 Teleconference.

Eagle



The Honorable Colm F. Connolly 21316

June 24, 2020

Page 2

Eagle anticipates having more information [REDACTED], after it has fully analyzed [REDACTED]. That said, Eagle does not believe [REDACTED] will bear on the legal case before your Honor, for which both parties are trial-ready.

Because Eagle may have additional information relating to [REDACTED] [REDACTED] we believe it makes sense for the Court and the parties to talk after Eagle has such information. Eagle will update the Court once it has more information and expects to request the Court to schedule a status conference after that update to discuss the scheduling of trial in this action.

Respectfully,

/s/ Bindu A. Palapura

Bindu A. Palapura

BAP:nmt/6776403/45185

cc: Counsel of Record (via electronic mail)

EXHIBIT E

REDACTED

EXHIBIT F

REDACTED

EXHIBIT G

REDACTED

EXHIBIT H

REDACTED

EXHIBIT I

REDACTED